No. 87-498-CFX
Status: GRANTED

Title: Kevan Berkovitz, a minor by his parents and natural guardians Arthur Berkovitz, et ux., et al., Petitioners
v.
United States

Docketed:
September 25, 1987

Court: United States Court of Appeals for the Third Circuit

Counsel for petitioner: Viakley,Ellen M.

Counsel for respondent: Solicitor General

Entry	Date	Note	Proceedings and Orders
1	Sep 25 1987	G	Petition for writ of certiorari filed.
3	Oct 26 1987		Order extending time to file response to petition until November 29, 1987.
4	Nov 19 1987		Order further extending time to file response tc petition until December 23, 1987.
5	Nov 19 1987		Order further extending time to file response to petition until December 23, 1987.
6	Dec 11 1987		Brief of respondent United States in support of petition filed.
7	Dec 16 1987		DISTRIBUTED. January 8, 1988
8	Jan 11 1988		Petition GRANTED.
			**********
9	Feb 10 1988		Record filed.
		*	Certified copy of briefs, appendix and partial proceedings received.
11	Feb 16 1988		Record filed.
		*	Certified copy of original record received.
12	Feb 25 1988		Joint appendix filed.
13	Feb 25 1988		Brief of petitioners Kevan Berkovitz, et al. filed.
14	Mar 11 1988		SET FOR ARGUMENT, Tuesday, April 19, 1988. (4th case).
15	Mar 25 1988		CIRCULATED.
16	Mar 28 1988	G	Motion of Lederle Laboratories for leave to file a brief as amicus curiae filed.
17	Mar 28 1988	X	Brief of respondent United States filed.
18	Apr 4 1988		Motion of Lederle Laboratories for leave to file a brief as amicus curiae GRANTED.
19	Apr 12 1988	X	Reply brief of petitioners Kevan Berkovitz, et al. filed.
20	Apr 19 1988		ARGUED.

87-498

No. ———

Supreme Court, U.S.
FILED
SEP 25 1987
JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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QUESTIONS PRESENTED

Under Section 262 of the Public Health Service Act, private manufacturers cannot produce, manufacture or sell biologic products, including poliovirus vaccines, without a federal license. Section 262(d) of the Act provides that a license may be issued by the regulating agency "only upon a showing that the . . . products . . . meet standards . . . prescribed in regulations."

The questions presented are:

I. Is the view of the Third or of the Eighth and Ninth Circuits correct regarding whether employees of the regulating agency under § 262 have discretionary power to license a biologic product which does not comply with the agency's safety regulations?

II. After *Varig*, does the discretionary function exception bar an FTCA action alleging that a federal employee knowingly violated the agency's own safety regulations?

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
TABLE OF AUTHORITIES	iv
OPINIONS BELOW	1
JURISDICTION	2
STATUTES INVOLVED	2
STATEMENT OF THE CASE	2
REASONS FOR GRANTING THE WRIT	5
I. There Exists An Irreconcilable Conflict Among The Third, Eighth And Ninth Circuit Courts Of Appeals On The Questions Presented	5
II. The Issues Are Of Exceptional Importance In Defining What Measure Of Agency Accountability Under the FTCA, If Any, Remains After *Varig*	11
CONCLUSION	13
APPENDIX	
A. Opinion of the United States Court of Appeals for the Third Circuit	1a
B. Opinion and order of the United States District Court for the Western District of Pennsylvania	28a
C. Statutes and Regulations	
1. 42 U.S.C. § 262(d)	41a
2. 21 C.F.R. 601.20(a)	41a

TABLE OF AUTHORITIES

Cases:	Page
Baker v. United States, 817 F.2d 560 (9th Cir. 1987)	5, 8, 9, 10
Campbell v. United States, 107 U.S. 407 (1882)	10
Collins v. United States, 783 F.2d 1225 (5th Cir. 1986)	11
Federal Election Comm. v. Democratic Senatorial Campaign Committee, 454 U.S. 27, 102 S.Ct. 38, 70 L.Ed.2d 23	10
Griffin v. United States, 500 F.2d 1059 (3d Cir. 1974)	6, 8
Heckler v. Chaney, —— U.S. ——, 105 S.Ct. 1649, 84 L.Ed.2d 714 1985)	10
Kaye v. United States, Civil Action No. 32-86-1002 (S.D. Ohio)	4, 11
Loge v. United States, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982)	5, 6
Parulski v. United States, Civil Action No. 87-0731 (M.D. Pa.)	4, 11
Red Lake Band of Chippewa Indians v. United States, 800 F.2d 1187, 1196 (D.C. Cir. 1986)	8
U.S. v. S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines), 467 U.S. 797 (1984)	*passim*

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

No. ——

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

The petitioners Kevan Berkovitz, a minor, by his parents and natural guardians Arthur Berkovitz, his wife, Donna Berkovitz, and Arthur Berkovitz and Donna Berkovitz, in their own right, respectfully pray that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Third Circuit, entered in the above-entitled proceeding on June 30, 1987.

OPINIONS BELOW

The opinion of the Court of Appeals for the Third Circuit is reported at 822 F.2d 1322 and is reprinted in the appendix, p. 1a, *infra.*

The opinion of the United States District Court for the Western District of Pennsylvania (Diamond, D.J.)

has not been reported. It is reprinted in the appendix, p. 28a, *infra.*

JURISDICTION

Invoking federal question jurisdiction, Petitioners brought this Federal Tort Claims suit against the United States in the Western District of Pennsylvania. The government filed a Motion to Dismiss or in the Alternative for Summary Judgment, asserting that the challenged conduct was discretionary and that pursuant to 28 U.S.C. § 2680(a), the court did not have subject matter jurisdiction to hear the claims. The motion was denied. On June 5, 1986, the District Court certified the question for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). On July 21, 1986, the Third Circuit entered an order accepting the appeal.

On appeal, the Third Circuit entered a judgment and opinion reversing the District Court's order and directing that the government's motion for summary judgment be granted. The judgment of the Court of Appeals was entered on June 30, 1987. Berkovitz' petition for rehearing or rehearing en banc was denied on July 22, 1987, with three judges indicating they would grant rehearing en banc. This petition was filed within ninety days thereafter.

The jurisdiction of this Court to review the judgment of the Third Circuit is invoked under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

Section 262(d) of the Public Health Service Act is reprinted in the appendix, p. 41a, *infra.*

STATEMENT OF THE CASE

On May 10, 1979, Kevan Berkovitz was given a dose of polio vaccine by his pediatrician in Charleroi, Pennsylvania. One month later, he contracted paralytic poliomyelitis. He was not yet three months old. The Com-

municable Disease Center, a United States agency, determined that Kevan's polio was caused by the live-virus vaccine he ingested, which had been licensed and approved for release by the federal government. Petitioners assert liability based on the government's conduct in licensing the vaccine for production and release, despite its known failure to comply with regulatory safety standards.

In 1944, Congress recognized that the unregulated use of biologic products, including live-virus vaccines, could present epidemic risks to the public health. Congress therefore directed that biologic products could not be produced or distributed by private manufacturers without a federal license. 42 U.S.C. § 262(a). The Department of Health and Human Services, through its Division of Biologic Standards (DBS), was empowered by Congress to issue a license:

> . . . only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. Licenses shall be issued, suspended, and revoked as prescribed by regulations.

42 U.S.C. § 262(d). The regulations similarly provide that a product license shall be issued "only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations." 21 C.F.R. § 601.20(a).[1]

In 1963, DBS issued a license for an attenuated live poliovirus strain which had been developed by Dr. Albert Sabin and tested in the Soviet Union. The regulation which was "designed to insure the continued safety, purity and potency" of original virus strains is found at

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[1] These regulations were formerly at 42 C.F.R. § 63.110, *et seq.*

21 C.F.R. § 630.10(b)(i)(2). The first allegation of Petitioner's Complaint is that the Sabin strain was not tested in accordance with these regulations, that its deficiencies were known to the agency prior to the issuance of the license, and that agency employees acted without lawful authority in issuing a license for this non-complying biologic product. Complaint ¶ 17(b), (c).

A product license is also required for each production seed virus, derived from a "passage" or replication of the original virus strain and used to manufacture vaccine monopools. Regulations prescribe the tests which must be performed by the manufacturer to assess the neurovirulence and genetic stability of the seed virus. Regulations also prescribe the results which must be objectively demonstrated before the seed can be licensed for vaccine production. As noted *supra*, DBS is empowered to issue the license only upon "examination of the product and upon a determination that the product complies with the standards prescribed in the regulations." 21 C.F.R. § 601.20(a).

Among the production seeds derived from the Sabin strain was a virus designated "45 B 85". This seed virus had not been subjected by the manufacturer to all required testing and had failed some of the tests which were performed. The second allegation of Petitioners' Complaint is that agency employees acted without lawful authority in licensing 45 B 85 for vaccine production, in the absence of the required showing that the virus had been subject to all required testing and complied with all regulatory standards.[2] Complaint ¶¶ 17(d), (e), (g), (h).

[2] Petitioners' counsel represent Plaintiffs in two other pending polio vaccine cases: *Parulski v. United States*, Civil Action No. 87-0731 (M.D. Pa.) and *Kaye v. United States*, Civil Action No. C2-86-1002 (S.D. Ohio). The vaccine administered in each of these cases was also derived from 45 B 85.

The final allegation of Petitioners' Complaint is that the Bureau of Biologics (DBS' successor agency) exercised its regulatory authority to test vaccine lots prior to release; that the agency employee who reviewed the test results knew that a vaccine lot, derived from 45 B 85 and containing Kevan's dose, was excessively neurovirulent; and that issuance of a lot release approval permitting the vaccine to be distributed to the public was improper.[3] Complaint ¶ 19(a), (b).

At each step of this process, an agency employee unlocked a door which had been closed by Congress. As the result of his ingestion of the vaccine thus produced, Kevan Berkovitz has been paralyzed in all of his limbs and suffers a severe scoliosis, or curvature, of his spine. His muscles have atrophied and contracted, pulling his limbs into a deforming posture. Because his paralysis prevents him from breathing, a tracheostomy was performed, cutting a hole in his throat through which he is maintained on a respirator. His injuries are permanent. Complaint ¶¶ 23, 24.

REASONS FOR GRANTING THE WRIT

I. There exists an irreconcilable conflict among the Third, Eighth and Ninth Circuit Courts of Appeals on the questions presented.

The opinion of the Third Circuit in this case is in direct conflict with *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987) and *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982), both polio vaccine cases. The divergence is a direct result of this Court's opinion in *U.S. v. S.A. Empresa de*

[3] Under 21 C.F.R. § 610.2(a), the agency may do its own confirmatory testing before issuing a lot release approval. Plaintiffs aver that both the manufacturer's and the agency's testing indicated that the lot in question was excessively neurovirulent. This section does not apply to the licensing of the strain and seed virus.

Viacao Aerea Rio Grandense, 467 U.S. 797, 104 S.Ct. 2755, 81 L.Ed.2d 660 (1984), hereafter *Varig*.

Prior to *Varig*, there was uniformity among the circuits in construing the duties of government under § 262. In *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974), the court held that § 262 imposed mandatory obligations on the regulating agency and that the agency's issuance of a lot release approval for an excessively neurovirulent vaccine was not protected conduct:

> [N]o discretion was conferred to disregard the mandatory regulatory command . . . Although Congress has provided that activity within the authority of a government official, if a 'discretionary function' may not be the basis of Government liability even if negligent or an abuse of discretion, Congress has not immunized such activity of it exceeds the authority conferred. Liability, in such cases, in predicated not on a negligent or unwise policy determination, but on the failure of Government employees to conform to and act consistently with the authority delegated.

Id. at 1069.

Similarly, in *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982), the Eighth Circuit held that:

> The Secretary has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public.

Id. at 1273.

Varig followed in 1984. Plaintiffs in *Varig* were injured when a trash receptacle in a commercial airliner caught fire. Plaintiffs first challenged the decision of the Secretary of Transportation to implement only a "spot-check" inspection system to monitor airline compliance with FAA regulations. The action of the Secretary in

choosing the spot-check system was found to be fully within her express statutory power[4] and therefore immune. *Varig*, *supra*, 104 S.Ct. at 2766. Plaintiffs also challenged the FAA's failure to inspect the aircraft in question. On this point, the Court held that "acts of FAA employees in executing the 'spot-check' program in accordance with agency directives are protected by the discretionary function exception as well." *Ibid.*

The distinctions between *Varig* and the case at bar are significant. For example, the FAA was expressly empowered by 49 U.S.C. § 1421(c) to "grant exemption from the requirements of any rule or regulation . . . if [the Administrator] finds that such action would be in the public interest". The regulations do not require a showing of regulatory compliance before the issuance of a certificate, so long as the Administrator finds that any regulatory deficiencies are compensated for by "other factors." Further, the FAA is expressly empowered to vary compliance monitoring "according to the circumstances" and to take "calculated risks" in administering the spot-check system. *Id.* at 2768-69.

By contrast, the statute and regulations here provide that the agency may issue a license *only* upon a showing that the product meets regulatory standards. Nowhere in the enabling legislation or regulations is the agency given the discretion to exempt live-virus vaccines from the requirements of the regulations. Nowhere do the regulations empower the agency to relax scrutiny of test data "according to the circumstances" or to take "calculated risks" regarding the safety of vaccine recipients. Unlike the FAA inspectors in *Varig*, the agency em-

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[4] 49 U.S.C. § 1421(a)(3)(c) specifically empowers the Administrator to prescribe reasonable regulations governing inspection of aircraft and "in the discretion of the Administrator, the period for, and the manner in, which such inspection . . . shall be made."

ployees here were acting *outside* the scope of express statutory and regulatory directives.[5]

These distinctions were disregarded, in an apparent attempt to defer to the Court's statement in *Varig* that whatever else the discretionary functon exception may include, "it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals." *Id.* at 2767.

We respectfully submit that it was this seeming intent to extend broad protection to regulatory conduct that impelled the panel majority here to overrule *Griffin*,[6] and troubled the Ninth Circuit in *Baker* with what had become a "close and difficult" question. *Baker v. United States, supra*, 817 F.2d at 564.

The panel majority in *Berkovitz* struggled to conform to the *result* reached in *Varig*, but did so only at the expense of a consistent rationale. The majority first addressed the government's argument that *Varig* provided a *per se* immunity for regulatory conduct.[7] Although

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[5] In *Red Lake Band of Chippewa Indians v. United States*, 800 F.2d 1187 (D.C. Cir. 1986), Judge Bork wrote that:

> A decision cannot be shielded from liability if the decision-maker is acting without actual authority. A government official has no discretion to violate the binding laws regulations or policies that define the extent of his [or her] official powers. An employee of the government acting beyond his [or her] authority is not exercising the sort of discretion the discretionary function exception was enacted to protect. This proposition is implied in *Varig* and *Dalehite* and has been uniformly followed.

Id. at 1196.

[6] *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974).

[7] See discussion, *infra*, at 11.

this argument was rejected, the majority had difficulty discerning what limits had been established by the case.

Berkovitz argued that agency employees do not have discretion to disregard mandatory commands in the agency's enabling statute and regulations and that Congress did not intend the discretionary function exception to immunize the disobedience of the Executive to an express legislative command.

The majority's response was to construe the statute and the regulations as non-mandatory, i.e., as conferring power to license *despite* regulatory non-compliance. If this language can be construed as non-mandatory, if the word "only" can be read by a court to mean "occasionally", then there is no way for Congress to command the obedience of a regulatory agency. The opinion thus accomplishes a *per se* protection for regulatory conduct, even while acknowledging that Congress did not intend such a result in enacting § 2680(a).[8]

In dissent, Presiding Judge Higginbotham wrote that the majority's analysis "disregards the clear command of federal law" expressed in § 262 (24a); "distorts" the discretionary function exception (26a); and "expand[s] the exception beyond the boundaries of any case reported to date" (23a).

The Ninth Circuit, construing the same statute and regulations and also employing *Varig* as its "map", reached the opposite result, concluding that the licensing of a non-compliance polio vaccine is not protected conduct:

> The government argues that the regulatory scheme in this case is similar to the scheme in *Varig*, and that the regulations being enforced in *Varig* were no less mandatory than those at issue here. How-

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[8] 28 U.S.C. § 2680(a), setting forth the discretionary function exception.

> ever, the government overlooks an important distinction. In *Varig*, the mandatory regulations govern the conduct of the airline, not the government . . . In this case the Secretary may not issue a license for manufacturing polio virus vaccine unless the relevant test data has been submitted . . . *Agency employees charged with enforcing polio virus vaccine safety standards must require the submission of the test data. As to that there is no discretion.*

Baker v. United States, *supra*, 817 F.2d at 566 (emphasis added). We respectfully submit that the analysis of the Ninth Circuit is correct.

The Third Circuit has misconstrued *Varig* and, in doing so, rendered a judgment that is inconsistent with this Court's historic regard for Congress' power to prescribe the obligations of administrative agencies. One example is the caveat added by (now) Chief Justice Rehnquist to his opinion in *Heckler v. Chaney*, —— U.S. ——, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985), observing that in protecting discretionary activity from judicial review under the Administrative Procedure Act, "Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers." *Id.*, 105 S.Ct. at 1657. The Court has consistently held that an agency may not, by regulation or otherwise, abridge or diminish the rights, duties and obligations defined by Congress. *Campbell v. United States*, 107 U.S. 407 (1882); *Federal Election Committee v. Democratic Senatorial Campaign Committee*, 454 U.S. 27, 32-33, 102 S.Ct. 38, 42, 70 L.Ed.2d 23 (1981).

The conflict between *Baker* and *Berkovitz* is stark; it is irreconcilable; and it calls into question the proper balance of power between Congress and the Executive in regulatory matters. If unresolved, it will continue to confound trial courts confronted with discretionary function cases, and the analytical rifts will only widen.[9] The issue therefore warrants review by this Court to insure uniformity of judgment among the federal courts.

II. The issues presented are of exceptional importance in defining what measure of agency accountability under the FTCA, if any, remains after Varig.

It is the position of the United States government that *Varig* extends the immunity of the discretionary function exception to *all* regulatory conduct. That position has been asserted of record in this case and in others involving the exception,[10] and will continue to be asserted by the government in regulatory cases. With the opinion in *Berkovitz*, the government has accomplished the functional equivalent of a *per se* rule.

It is respectfully submitted that if *Varig* did intend to sweep so broadly and to protect all regulatory conduct, the Court's extensive discussion of the underlying statutory and regulatory bases for the agency's conduct would have been superfluous. Moreover, such a reading is not supported by the language of 28 U.S.C. § 2680(a), defining the exception. If Congress had intended to protect all regulatory acts, they could very easily have done so. The statute would simply have read: "All activities of federal regulatory agencies are exempt." The words "discretionary function" would have been unnecessary. The purposeful use of these words indicates that Congress' intent was to protect only the exercise of express discretionary *power*.

If there are limits to *Varig*—if there is still a category of regulatory conduct for which the government may be

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[9] Motions to Dismiss are pending in the polio cases cited *supra* at note 2. The *Parulski* motion has been stayed pending the Court's response to this petition. The *Kaye* motion, which was filed on October 30, 1986, remains pending.

[10] *E.g.*, *Collins v. United States*, 783 F.2d 1225 (5th Cir. 1986).

held accountable—we respectfully submit that the Court should take this opportunity to define them, and to put to rest the government's claim of *per se* regulatory immunity.

The case presented here would be a good prism for refraction and analysis of the issue. The questions are narrowly drawn: (1) do the statute and regulations confer discretionary power to license non-complying biologic products; and (2) is agency conduct which exceeds the scope of express statutory and regulatory authority protected? Further, the statutory and regulatory language is straightforward; and the factual record is limited to the allegations of the complaint, which must be accepted as true.

This case is also significant because it has called into question the duties of government with respect to regulation of biologic products. Such products, including live-virus vaccines and organisms created by genetic manipulation, can present epidemic risks to the public health. One poliovirus monopool generates one million doses of live-virus vaccine, capable of producing contagious and morbid disease in the adults and healthy school children who are required to take it. That is precisely why Congress directed that biologic products cannot be licensed unless they are demonstrated to meet objective regulatory standards designed to insure their continued safety. There may not be another section in all of the U.S. Code that imposes so stringent a duty on the regulating agency.

The decision below sets agency employees free to disregard congressional intent and objective regulatory standards and to act instead according to their own subjective judgment of the more expedient course. Exceptional importance attaches to this decision, not only because it jeopardizes the proper and uniform administration of federal law, but also because of the broad potential for harm inherent in the release of defective biologic products.

CONCLUSION

For the reasons stated above, Petitioners Kevan Berkovitz, and Arthur and Donna Berkovitz, his parents, respectfully request this Honorable Court to grant their Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

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APPENDICES

APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 86-3444

KEVAN BERKOVITZ, a minor by his parents and natural guardians ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ, and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right

v.

UNITED STATES OF AMERICA,
Appellant

On Appeal from the United States District Court
for the Western District of Pennsylvania
(D.C. Civil No. 84-2893)

Argued February 19, 1987

BEFORE: HIGGINBOTHAM and SLOVITER,
Circuit Judges,
and ROTH, *District Judge**

(Opinion Filed June 30, 1987)

---

* Honorable Jane R. Roth, United States District Court for the District of Delaware, sitting by designation.

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OPINION OF THE COURT

SLOVITER, *Circuit Judge.*

I.

Issue

In *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974), this court held that a suit alleging negligence on the part of the Division of Biologic Standards (DBS) in approving for production and distribution a polio vaccine which subsequently caused the plaintiff's paralysis was not barred by the discretionary function exception to United States liability under the Federal Tort Claims Act (FTCA). In *United States v. S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984), the Supreme Court held that the discretionary function exception barred an FTCA suit based on the negligence of the Federal Aviation Administration (FAA) in certifying an aircraft that did not comply with applicable safety regulations. The FTCA action before us makes allegations of government negligence virtually indistinguishable from those asserted in *Griffin*. The question before us on this interlocutory appeal is whether our holding in *Griffin* remains binding following the Supreme Court's pronouncement in *Varig* on the scope of the discretionary function exception.

II.

Facts

The government sought and was granted certification pursuant to 28 U.S.C. § 1292(b) of the district court's order denying its motion to dismiss this action for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). The district court was obliged to accept the

factual averments of the complaint as true for purposes of the motion. *See Curtis v. Everette*, 489 F.2d 516, 518 (3d Cir. 1973), *cert. denied*, 416 U.S. 995 (1974). Our review is plenary. Berkovitz's amended complaint alleges the following facts.

Kevan Berkovitz, a minor, received a dose of Orimune, a Sabin Oral Poliomyelitis Vaccine manufactured by Lederle Laboratories (Lederle), on May 10, 1979 and contracted paralytic poliomyelitis within a month. The Communicable Disease Center, a United States agency, determined that Berkovitz had contracted polio from the vaccine.

Prior to 1972, the Division of Biologic Standards (DBS), a division of the National Institutes of Health, licensed Lederle to produce a trivalent oral vaccine using live virus of the Sabin strains. Lederle then developed from the original Sabin strains a seed virus which DBS licensed it to produce despite the fact that it did not satisfy standards for neurovirulence set forth in the regulations applicable to live polio vaccines. After 1972, a division of the Food and Drug Administration (FDA) took over responsibility for approval and licensure of live polio vaccines. The FDA approved a monopool of virus [1] developed from the defective seed virus for use in production despite the fact that the monopool was tested and found to exceed the applicable standards for neurovirulence. This defective monopool was subsequently used by Lederle in the manufacture of the lot of trivalent oral polio vaccine, Orimune, administered to Berkovitz.[2]

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[1] There are three types of the Sabin strains of poliovirus: Types I, II and III. A monopool is a single type. When monopools of the three types are combined, they form a trivalent vaccine.

[2] Although the government contends that it followed all mandatory regulations in licensing Lederle to produce Orimune and in approving for production and release the lot of vaccine administered to Berkovitz, it agrees that for purposes of this appeal, we must assume Berkovitz's allegations of negligence to be true. Appellant's Brief at 4 n.3.

Berkovitz (joined by his parents as his guardians) filed a complaint in federal district court, after following the requisite administrative procedure. The complaint asserts a claim against the United States under the Federal Tort Claims Act for the negligence of DBS in licensing and of the FDA in approving for release the live polio vaccines.[3] Specifically, Berkovitz alleges that he suffered damages as a result of: 1) the negligence of DBS in licensing Lederle for the original Sabin strains; 2) the negligence of the FDA in approving for production and release the lot of trivalent vaccine manufactured from the defective monopool; 3) the negligence of the FDA in failing to withdraw the defective vaccine from the market; and 4) the negligence of the FDA in failing to require Lederle to warn of the risks of the defective vaccine.

The government moved for dismissal for lack of subject matter jurisdiction on the grounds that the agency actions challenged fall within the discretionary function exception to the United States' waiver of sovereign immunity under the FTCA. In ruling on the government's motion, the district court relied on this court's prior decision in *Griffin*:

> In *Griffin*, the plaintiff sustained personal injuries resulting from the ingestion of a [vaccine] which did not conform to the defendant's regulations. The Third Circuit concluded that the government was not immune from suit pursuant to the discretionary function exception . . . since the government employee's conduct in implementing agency regulations required only scientific evaluation and not the formulation of policy.

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[3] Berkovitz also initiated an action against Lederle. That action was settled.

App. at 51-52. The court rejected the government's argument that the *Griffin* holding does not survive the Supreme Court's subsequent decision in *Varig*. The district court stated that under Third Circuit Internal Operating Procedure 8.C., "no matter how persuasive the arguments may be that *Griffin* is no longer valid, we are bound to apply the principles in *Griffin*." App. at 55. Applying those principles, the court concluded that the discretionary function exception barred Berkovitz's claims of "alleged failure to warn and withdraw the product" but did not bar Berkovitz's claims of "negligent licensure and approval" of either the original Sabin strains or the lot of vaccine administered to Berkovitz. App. at 56.[4]

III.

The Legal Background: Griffin *and* Varig

Under the FTCA, the United States waives its sovereign immunity from suit for compensatory damages for personal injury resulting from the conduct of a government employee acting within the scope of his employment. 28 U.S.C. §§ 1346(b), 2674. One of the exceptions to which that waiver is subject provides that the United States does not waive its sovereign immunity from actions "based upon the exercise or performance of or the failure to exercise or perform a discretionary function or duty." 28 U.S.C. § 2680(a). We have treated the discretionary function exception as establishing a jurisdictional bar. *See Smith v. Johns-Manville Corp.*, 795 F.2d 301, 306 n.8 (3d Cir. 1986); *Gibson v. United States*, 457 F.2d 1391, 1392 n.1 (3d Cir. 1972). The government contends that Berkovitz's action falls within the discretionary function exception and is barred by the United States' sovereign immunity.

[4] On appeal, Berkovitz concedes that his claims for negligent failure to warn or withdraw are barred by the discretionary function exception. Appellee's Brief at 3.

Reading Berkovitz's complaint in the way most favorable to Berkovitz, it is clear that, at least in part, Berkovitz alleges a violation of regulations identical to those at issue in *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974). Griffin, who had contracted polio after ingesting a Sabin type polio vaccine, sued the United States alleging DBS negligence in releasing the vaccine at issue. At that time, as now, agency regulations allowed release of vaccine only if, after a "comparative evaluation" of five criteria with a reference strain of vaccine, "a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the NIH Reference . . . ." *Id.* at 1062-63 n.7 (quoting 42 C.F.R. § 73.114(b)(1)(iii) (1974) (now codified at 21 C.F.R. § 630.16(b)(1)(iii) (1987))). Tests performed by DBS indicated that the vaccine at issue displayed greater neurovirulence than the reference on all five enumerated criteria. *Id.* at 1067 & n.18. Griffin contended that DBS could be held liable for its release of the vaccine in violation of its own regulations. The government contended both that the decision to release the lot of vaccine in question involved the exercise of a discretionary function and that "Congress intended, by the discretionary function exception . . ., to exclude all claims 'arising from acts of a regulatory nature.'" *Id.* at 1063.

We noted that "accepting the Government's [latter] contention would effectively immunize all Governmental activity from judicial review except the most ministerial acts." *Id.* at 1063-64. Instead we construed the decision in *Dalehite v. United States*, 346 U.S. 15 (1953), as limiting, the discretionary function exception to activity involving "considerations of public policy", 500 F.2d at 1064, focusing on the Court's statement in *Dalehite* that "[w]here there is room for policy judgment and decision, there is discretion." 346 U.S. at 36 (quoted in 500 F.2d at 1064).

Although we accepted DBS' construction of its regulations as allowing "judgmental determination as to the degree to which each of the enumerated criteria indicated neurovirulence in monkeys," we concluded that this was "a scientific, but not policy-making, determination." 500 F.2d at 1066. We pointed out that "responsibility was limited to merely executing the policy judgments of the Surgeon General." *Id.*

For this reason, we concluded that DBS' discretion in "performance of scientific evaluation" did not justify immunization from judicial review. *Id.* Moreover, we noted that DBS had no discretion "to disregard the mandatory regulatory command" under the "biological variation" rubric that it had applied and that DBS had exceeded its authority under the regulations by "discounting test results that were required to be considered significant." *Id.* at 1068. We concluded:

> We do not hold that the Government may be liable for policy determinations made by its officials. Rather, we hold only that the Government may be liable where its employees, in carrying out their duties, fail to conform to pre-existing statutory and regulatory requirements.

Id. at 1069.

In this case, Berkovitz's complaint alleges a failure by the government to insure Lederle's compliance with "applicable reguluations, including, but not limited to: . . . 42 C.F.R. 73.114(b)(1)(iii)," App. at 29, the same regulation at issue in *Griffin*. Thus, if we are still bound by our holding in *Griffin* that release of a vaccine lot that does not satisfy regulatory criteria is not a discretionary function, Berkovitz's action under the FTCA may be maintained. *See* Internal Operating Procedures of the Court of Appeals for the Third Circuit, Chapter 8.C., discussed in *Poulis v. State Farm Fire & Casualty Co.*, 747 F.2d 863, 867 (3d Cir. 1984). On the other hand,

if an intervening Supreme Court decision mandates a different result, we may not "countenance the continued application in this circuit of a rule, even of our own devising, which is patently inconsistent with the Supreme Court's pronouncements." *Cox v. Dravo Corp.*, 517 F.2d 620, 627 (3d Cir.), *cert. denied*, 423 U.S. 1020 (1975). *See also McMahon v. McDowell*, 794 F.2d 100, 108 (3d Cir.), *cert. denied*, —— U.S. ——, 107 S. Ct. 473 (1986). The government contends that because of the intervening decision in *United States v. S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984), *Griffin* is no longer binding law.

In *Varig* and *United States v. United Scottish Insurance Co.*, 467 U.S. 797 (1984), decided in the same opinion, plaintiffs claimed that their injuries or damages from aircraft accidents had resulted from the negligence of the Federal Aviation Administration (FAA) and its predecessor, the Civil Aeronautics Agency (CAA), in approving aircraft designs. Congress granted the FAA authority to exercise its discretion in promulgating regulations governing inspection and licensing of aircraft. The FAA responded with a system under which manufacturers remain responsible for testing and compiling data, while the FAA receives the data for review and retains the option of performing spot-inspections with its own staff or surrogate representatives.

In *Varig*, the FAA had inspected the Boeing 707 before issuing a type certificate approving the aircraft design, but it apparently approved the aircraft at various stages without inspecting the design of the lavatory towel disposal receptacle which did not satisfy applicable safety regulations. The failure of that receptacle to contain a fire proved fatal to 124 persons on board the Boeing 707 aircraft involved in the accident. In *Scottish*, the FAA had approved, without performing its own inspection, an aircraft modification involving installation of a cabin

heater which did not meet applicable safety regulations. That heater was the cause of a fire.

In considering the applicability of the discretionary function exception, the Court isolated two relevant factors useful in determining when the exception applies. "First, it is the nature of the conduct, rather than the status of the actor, that governs whether the discretionary function exception applies in a given case". *Id.* at 813. The Court stated that the basic inquiry is whether "the challenged acts of a Government employee—whatever his or her rank—are of the nature and quality that Congress intended to shield from tort liability." *Id.* The second factor was that the exception "plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals." *Id.* at 813-14. The Court noted that "Congress wished to prevent judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort." *Id.* at 814.

Applying this standard, the Court noted that what was at issue was the failure of the FAA to actually inspect the aspects of the design to which the fires were attributable. The Court construed plaintiffs' claims as challenging "the FAA's decision to implement the 'spot-check' system of compliance review, and the application of that 'spot-check' system to the particular aircraft." *Id.* at 819. The Court concluded that the FAA's implementation of a mechanism for compliance review is plainly discretionary activity because, "[w]hen an agency determines the extent to which it will supervise the safety procedures of private individuals, it is exercising discretionary regulatory authority of the most basic kind." *Id.* at 819-20. It followed that "the acts of FAA employees in executing the 'spot-check' program in accordance with agency directives are protected" because the FAA employees were

empowered to decide how much confidence to place in a given manufacturer's procedures. *Id.* at 820.

Following *Varig*, this court has twice questioned the continued vitality of *Griffin*. In *General Public Utilities Corp. v. United States*, 745 F.2d 239 (3d Cir. 1984), *cert. denied*, 469 U.S. 1228 (1985) (*GPUC*), the owners of the Three Mile Island nuclear facility filed an FTCA suit based on the failure of the Nuclear Regulatory Commission to investigate an occurrence at another nuclear plant and to communicate warnings based thereon. We held that the claims were barred because the Commission exercised discretion in making policy determinations to decide when occurrences were significant enough to warrant investigation and warning. *Id.* at 244-46. We rejected plaintiffs' attempted reliance on *Griffin* as "excluding professional and scientific judgments from the discretionary category" both because "*Griffin* . . . must be read cautiously because in *Varig* the discretionary exception covered an agency decision that rested on highly technical information" and because the Commission exercised discretion in making non-technical judgments as to public health and safety. *Id.* at 246.

Thereafter, in *Smith v. Johns-Manville Corp.*, 795 F.2d 301 (3d Cir. 1986), we again noted that *Griffin's* distinction between scientific evaluation and policy judgments must be read cautiously in light of *Varig*. *Id.* at 309 & n.13. In that case, defendants who were sued by present and former employees of Johns-Manville for injuries resulting from 'exposure to asbestos filed third-party claims against the United States under the FTCA based on the General Services Administration's failure to label asbestos sold to them as part of the government's asbestos disposal scheme. We rejected the third party plaintiffs' claim that the failure to warn, when isolated from the overall decision to dispose of the asbestos "as is," involved no policy judgment. We construed *Dalehite* as precluding this type of compartmentalization of agency decisions,

and concluded that, when considered as a whole, implementation of the disposal scheme required the GSA to exercise discretion to "avoid market disturbances" and "maximize the government's revenues." *Id.* at 308. Because these were policy decisions, the discretionary function exception precluded the third party claims. *Id.* at 308-09.

Although the opinions in *GPUC* and *Smith* suggest that *Griffin* must be reevaluated in light of *Varig*, we had no occasion to decide whether *Griffin* is effectively overruled, a position the government now urges us to adopt.

IV.

Does Varig require immunity for all regulatory activity?

The government has asked us to interpret *Varig* to mean that the discretionary function exception "was intended to apply to all claims arising from the regulatory activities of federal agencies." Appellant's brief at 18. Initially, the government relies on the statement in *Varig* that "whatever else the discretionary function exception may include, it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals." 467 U.S. at 813-14. In addition, the government points to this court's statement in *Smith* interpreting *Varig* as requiring that where "the challenged conduct involves the government acting in its capacity as a regulator of individual conduct, the exception presumptively applies." 795 F.2d at 307.

We do not accept this per se approach. The Fifth Circuit rejected the government's per se interpretation because it ignores the fact that "not all regulatory conduct is discretionary conduct." *Collins v. United States*, 783 F.2d 1225 (5th Cir. 1986). We agree. The plain language of *Varig* states that the exception applies only to "discretionary acts" of regulators. Our view that the

discretionary function exception is inapplicable to non-discretionary regulatory actions accords with the legislative history which indicates that the exception is "designed to preclude application of the act to a claim based upon an alleged abuse of discretionary authority by a regulatory or licensing agency. 467 U.S. at 809 (quoting Hearings on H.R. 5373 and H.R. 6463 before the House Committee on the Judiciary, 77th Cong., 2d Sess. 28, 33 (1942) (statement of Assistant Attorney General Shea)). If Congress intended to except all regulatory actions from the scope of the FTCA, we are confident it would have said no.

We do not construe the decision in *Bacon v. United States*, 810 F.2d 827 (8th Cir. 1987), as adopting a per se exception for regulatory conduct, as the government suggests. There, a group of road workers filed an FTCA action alleging negligence by the Department of Housing and Urban Development and the Environmental Protection Agency in failing to warn them of the presence of dioxin. In upholding the judgment of the United States under the discretionary function exception, the court did not rely on any per se exemption, but instead reasoned that appellants' claim was based on a failure to perform a discretionary function, i.e. to warn. *Id.* at 830.

Nor do we believe the government's broad position is supported by *Hylin v. United States*, 755 F.2d 551 (7th Cir. 1985) (*Hylin II*), *following remand from* 469 U.S. 807 (1984). In that opinion, the court directed dismissal of a complaint alleging negligence by a mine inspector in failing to discover a mine operator's non-compliance with mandatory safety regulations. The court held that the discretionary function exception precluded suit because the statute reposed discretion in the mine inspectors to determine both whether non-compliance represented an imminent danger and how and when to require compliance. *Id.* at 554.

If, as the government argues, all regulatory action is per se removed from the FTCA, there would have been no need for the *Bacon* and *Hylin II* decisions, upon which the government relies, to have focused on the discretionary nature of the regulatory acts at issue. Moreover, the post-*Varig* decisions in this circuit would not have made the same inquiry. *See, e.g., Pooler v. United States*, 787 F.2d 868, 871 (3d Cir.), *cert. denied*, —— U.S. ——, 107 S. Ct. 175 (1986) (investigator of drug distribution in a federal hospital had discretion to select, use, and control an informant); *GPUC*, 745 F.2d at 246 (applying exception because agency had discretion to weigh technical and scientific data as well as concerns with public health and safety before choosing a course of action).

Following *Varig*, several Court of Appeals cases have permitted maintenance of FTCA suits based on negligent performance of regulatory agencies, thereby implicitly if not explicitly rejecting the per se theory the government urges us to adopt. *See, e.g., Baker v. United States*, 817 F.2d 560, 565 (9th Cir. 1987); *Red Lake Band of Chepewa Indians v. United States*, 800 F.2d 1187, 1197 & n.3 (D.C. Cir. 1986); *Collins v. United States*, 783 F.2d 1225, 1229 (5th Cir. 1986).

In *Merklin v. United States*, 788 F.2d 172 (3d Cir. 1986), we made the distinction between cases where no policy judgment was implicated and the case before us there where the agency action at issue, the Atomic Energy Commission's failure to warn in connection with plant inspections, was the subject of its "unbounded" discretion in conducting plant inspections. *Id.* at 175. *See also C.P. Chemical Co. v. United States*, 810 F.2d 34, 39 (2d Cir. 1987) (exception applies because "this is *not* a case where an agency ignored its own regulations or the clear mandate of statutory procedure"); *Heller v. United States*, 803 F.2d 1558, 1563 (11th Cir. 1986) (("if a government official in performing his statutory

duties must act without reliance upon a fixed or readily ascertainable standard, the decision he makes is discretionary and within the discretionary function exception. Conversely, if there is a standard by which his action is measured, it is not within the exception") (citations and emphasis omitted). We therefore construe *Varig* as requiring the courts to distinguish between those FTCA suits based on regulatory actions which are discretionary, and which therefore cannot be maintained, and those based on alleged negligence in the performance of a non-discretionary regulatory action.

V.

Application of the Discretionary Function Exception

We must therefore address Berkovitz's contention that he has alleged negligent acts or omissions taken in violation of regulations imposing non-discretionary duties. Berkovitz's complaint alleges negligence both by DBS in licensing Lederle for manufacture of live oral vaccine using the Sabin strains, which, it alleges did not meet mandatory regulatory standards, and by FDA in approving release of a vaccine lot produced from a defective seed virus and monopool. For purposes of this decision, we need not treat separately the licensing claim and the lot release claim.

The regulations at issue here are essentially the same as those that were in effect at the time of the *Griffin* decision, where we upheld government liability for negligent approval of a production lot of a vaccine. *Compare* 21 C.F.R. §§ 601.1-601.4, 601.20, 610.1-610.2, 630.10-630.16 (1987) *with* 42 C.F.R. §§ 73.3, 73.5, 73.9, 73.70, 73.76, 73.110-73.117 (1968).[5] The government argues

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[5] In *Griffin*, we did not address the licensing claim. The district court in that case had found that the August 24, 1960 approval by the Surgeon General of the Sabin strains for use in the United States was "properly discretionary, since no regulation then in

that *Varig* undermines the *Griffin* analysis because the FDA is under no non-discretionary duty to enforce its safety regulations.

After *Varig*, it is clear that the discretionary function exception exempts the United States from claims based on 1) discretionary planning level acts and omissions, *e.g.*, *Merklin*, 788 F.2d at 174 (warning not mandatory under Atomic Energy Act); 2) discretionary operational level acts and omissions, *e.g.*, *GPUC*, 745 F.2d at 244-47 (Commission's discretionary implementation of statutory direction to review safety); and 3) non-discretionary operational level acts and omissions taken in furtherance of planning level discretionary decisions, *see Dalehite v. United States*, 346 U.S. 15, 35-36 (1953).

It is also clear after *Varig* that an agency's promulgation of a regulation specifying standards governing a matter subject to regulation does not without more make the discretionary function exception inapplicable. The necessary inquiry in such a situation is whether the agency retains the discretion whether or how to enforce that regulation. *See GPUC*, 745 F.2d at 244.

The government argues that the safety regulations governing live polio vaccine leave at least as much enforcement discretion to the FDA as the regulations at issue in *Varig* left to the FAA. For this reason, the government contends, the discretionary function exception must apply to FDA approval of polio vaccine even though we must assume for this purpose that the vaccine failed to meet substantive safety requirements set out in the FDA regulations.

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effect foreclosed such a judgment." Griffin v. United States, 351 F. Supp. 10, 26 n.20 (E.D. Pa. 1972). Because the regulations governing Lederle's licensure for production upon which Berkovitz relies were not promulgated until November 23, 1961, *see id.* at 26, the issue before us on licensing is a different one than that before the *Griffin* district court.

The regulations of the FDA and FAA are similar in the allocation of responsibility for compliance with explicit safety regulations. In *Varig*, the Court stated that the FAA certification process is founded upon the notion that "the duty to ensure that an aircraft conforms to FAA safety regulations lies with the manufacturer and operator," 467 U.S. at 816. Similarly, the FDA puts the initial responsibility for testing on the manufacturer. *See* 21 C.F.R. § 610.1 (1987) ("[N]o lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies"); 21 C.F.R. § 601.2 (1987) ("manufacturer . . . in the case of an application for a product license, shall submit data . . . which demonstrate that the manufactured product meets prescribed standards of safety"); 21 C.F.R. § 630.10(b)(4) (1987) ("[t]he neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer"); *see also* 42 C.F.R. §§ 73.3, 73.70, 73.110(b)(4) (1968).

The tests to which these regulations apply are those that Berkovitz contends the Lederle virus failed. *See* 21 C.F.R. § 630.10(b)(2) (1987) ("Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine Live Oral, unless . . . each such strain produces a vaccine meeting the safety and potency requirements of §§ 630.11, 630.15 and 630.16(b); *see also* 42 C.F.R. § 73.110(b)(2) (1968) (requiring same tests set out at 42 C.F.R. §§ 73.114(b), 73.115, 73.117). It is therefore evident that looking at the regulations as a whole, it is the manufacturer that is required to perform the tests.

Berkovitz can point to no regulation requiring the FDA to do anything. In other words, no regulation im-

poses a non-discretionary duty.[6] Berkovitz points to the statutory requirement that licenses for products may be issued:

> only upon a showing that . . . the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards.

42 U.S.C. § 262(d); *see also* 21 C.F.R. § 601.20(a) (1987) ("[a] product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations in this subchapter"); 42 C.F.R. § 73.5 (1968). Berkovitz contends that the FDA, unlike the FAA, is under a statutory duty to "insure" compliance with its safety regulations. Judge Higginbotham's dissenting opinion also views the statute as imposing a "clear command of federal law" because it creates a duty by the FDA to receive the showing that the vaccine manufacturer must make to the government. However, the FDA's statutory duty is not different in substance from the duty that the Supreme Court in *Varig* found rests with the FAA.

Two illustrations from the statute at issue in *Varig* will suffice to show the duty imposed on the FAA with

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[6] In *Baker*, 817 F.2d at 566, the court read 42 U.S.C. § 262(d) and 21 C.F.R. § 630.10(b)(2) as imposing on the FDA a mandatory duty to "not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted." Therefore, it held that the plaintiff's allegation of a negligent failure to require submission of test data was not covered by the discretionary function exception. Here, Berkovitz's complaint can be read as alleging a similar falure to require submission of test data. *See* App. at 30-31. We do not agree, however, that the FDA is under a duty to require submission of test data. Rather, the duty to submit test data rests with the manufacturer. *See* 21 C.F.R. §§ 601.2, 610.1, 630.10(b)(4) (1987).

respect to receipt of the manufacturer's showing of compliance is similar to the duty on which Judge Higginbotham relies. The applicable statute provides, *inter alia*.

> The Secretary of Transportation shall make, or require the applicant to make, such tests during manufacture and upon completion as the Secretary of Transportation deems reasonably necessary in the interest of safety, including flight tests and tests of raw materials or any part or appurtenance of such aircraft, aircraft engine, propeller, or appliance. If the Secretary of Transportation finds that such aircraft, aircraft engine, propeller, or appliance is of proper design, material, specification, construction, and performance for safe operation, and meets the minimum standards, rules, and regulations prescribed by the Secretary of Transportation, he shall issue a type certificate therefor.

49 U.S.C. § 1423(a)(2). Another section provides:

> Upon application, and if it satisfactorily appears to the Secretary of Transportation that duplicates of any aircraft, aircraft engine, propeller, or appliance for which a type certificate has been issued will conform to such certificate, the Secretary of Transportation shall issue a production certificate authorizing the production of duplicates of such aircraft, aircraft engines, propellers, or appliances. The Secretary of Transportation shall make such inspection and may require such tests of any aircraft, aircraft engine, propeller, or appliance manufactured under a production certificate as may be necessary to assure manufacture of each unit in conformity with the type of certificate or any amendments or modification thereof.

49 U.S.C. § 1423(b). The Supreme Court recognized in *Varig* that "the FAA retains the responsibility for policing compliance", 467 U.S. at 816, but did not interpret

this responsibility as the type of mandate that makes the discretionary function analysis inapplicable. The Supreme Court's treatment of the discretionary function exception in the context of that statute, therefore, also governs our interpretation of the analogous FDA statute. It would be incongruous to conclude that Congress intended the FAA to exercise a lesser supervision over the safety of aircraft than the FDA was to exercise over the safety of polio vaccine, which is what the dissent appears to suggest.

In *Varig*, the Supreme Court concluded that "[t]he FAA's implementation of a mechanism for compliance review is plainly discretionary activity of the 'nature and quality' protected by § 2680(a)." 467 U.S. at 819. Reviewing the regulations at issue here, it is evident that in exercising a similar discretion, the FDA has made a policy choice to leave compliance in the first instance to the manufacturer. The FDA enters the verification process only if it exercises its discretion under the regulations to examine manufacturer data or perform its own tests. *See* 21 C.F.R. § 610.2(a) (1987) (FDA may demand samples from manufacturer for use in own testing prior to approval); 42 C.F.R. § 73.76 (1968); *see also Griffin*, 500 F.2d at 1065 n.11 (practice of DBS to perform own tests "because of the lack of reliability of the manufacturers' test results").

In the instant case, the allegations is that the FDA exercised its discretion to verify compliance and then negligently erred in finding compliance. If true, this case would be distinguishable from *Varig* where the agency failed to inspect and did not know of the noncompliance. Here the FDA allegedly discovered the defect. Berkovitz argues that once the FDA had information that the vaccine did not comply with the regulations, it had no discretion to approve either the license for production or the lot for release. There is a certain facial attraction to this

contention. On examination, however, this argument is simply that the FDA acted negligently. Indeed, Berkovitz's contention that the FDA was obliged to disapprove the noncomplying vaccine once it learned of the noncompliance is rejected by the Supreme Court's vacation of the *Hylin I* decision where the Court of Appeals had held that the discretionary function exception was inapplicable to the negligent inspection of a mine. *See Hylin v. United States* (*Hylin I*), 715 F.2d 1206, 1213-14 (7th Cir. 1983), *vacated and remanded in light of Varig*, 469 U.S. 807 (1984). On remand, the court held that notwithstanding the inspector's negligence in advising how to correct a known safety risk, the discretionary function exception applied. *Hylin II*, 755 F.2d at 553-54. As we have stated, "the issue of negligence is not relevant to the discretionary function inquiry." *GPUC*, 745 F.2d at 243.

Moreover, even if the FDA had decided to methodically examine test results or test vaccine samples itself rather than follow the FAA's decision to spot-check aircraft compliance, this would be a discretionary decision. If we were to hold that an agency's discretionary choice to test all samples subjects the United States to liability whenever in testing the agency negligently fails to recognize and remove noncomplying products, we would inhibit the agency's selection of the mechanism for compliance review. This is precisely what *Varig* instructs us not to do. It follows that when the FDA makes the discretionary choice to examine or test samples which it has discretion not to test, it cannot be held liable for subsequent negligence at the operational level in implementing its decision to test.

In short, Berkovitz has failed to allege a violation of a non-discretionary duty imposed on the FDA by statute or regulations and therefore the discretionary function exception applies.

IV.

Conclusion

In summary, *Griffin* isolated one regulation, looked at what appears on its face to be mandatory language, and held that in light of that mandatory language the discretionary function exception was inapplicable. We do not disturb the portions of *Griffin* that hold that an agency's violation of its own mandatory regulation is not a discretionary act. However, *Varig* instructs that a court must determine whether "the basic responsibility for satisfying [the agency's] safety standards rests with the *manufacturer*," and whether "[t]he role of the [agency] . . . is merely to police the conduct of private individuals by monitoring their compliance with [the applicable] regulations." 467 U.S. at 815. We have interpreted *Varig* as requiring this determination to be made by examining agency regulations as a whole.

In light of *Varig*, it is necessary to reevaluate the holding in *Griffin*. The inquiry required by *Varig* demonstrates that the responsibility for compliance with the regulations Berkovitz alleges were violated was that of Lederle, and neither the statute nor the regulations mandate the FDA's choice of how to secure Lederle's compliance. We will therefore reverse the district court's order denying the government's motion for summary judgment and remand with instructions that the court grant that motion.

A. LEON HIGGINBOTHAM, JR., *Circuit Judge*, dissenting.

The amended complaint alleges the following: At the age of approximately two months, Kevan Berkovitz was administered the Sabin oral polio vaccine by his pediatrician. Less than one month later, this vaccine caused him to sustain a case of paralytic poliomyelitis. Among the disease's many consequences is a curvature of Berkovitz's spine as great as ninety degrees. He requires ventilatory assistance to breathe, and he has lost the use of his arms, legs and hands. These injuries are permanent.

While this is an extremely difficult case, to my view the majority's tilt ignores the clear statutory language that defines the duty of the Division of Biologic Standards ("DBS") to require the submission of test data. By not requiring the government to comply with a statute designed to insure the "safety, purity, and potency" of these drug products, the majority has expanded the discretionary function exception beyond the boundaries of any case reported to date. I respectfully dissent.

The regulations in this field place mandatory duties upon a drug manufacturer, such as Lederle, that seeks to obtain a federal license to market its drug product. First, the manufacturer must make its license application to the Director of the Office of Biologics Research and Review on the forms prescribed by regulations. 21 C.F.R. § 601.2(a) (1987). Second, such application forms must be accompanied by "data derived from nonclinical laboratory and clinical studies [that] demonstrate that the manufactured product meets prescribed standards of safety, purity and potency. . . ." *Id.* Third, where the manufacturer is seeking a license for Poliovirus Vaccine Live Oral, the data to be submitted must "establish that each [poliovirus] strain is free of harmful effect upon administration in the recommended dosage to at least 1 million people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance

of neurological illness has been maintained. . . ." 21 C.F.R. § 630.10(b)(2) (1987). Fourth, the manufacturer must "demonstrate[]" the neovirulence of each seed virus used in its vaccine with data garnered in its performance of a specific series of tests. 21 C.F.R. § 630.10 (b)(4) (1987).

As the majority has recognized, "Berkovitz's complaint can be read as alleging a [negligent] failure [by DBS] to require submission of test data." Maj. typescript at 22 n.6. In addition, Berkovitz's amended complaint can be read as alleging a decision by DBS to license Lederle's manufacture of this vaccine, even though the test data submitted showed that certain monovalent virus pools had failed the required neovirulence tests.[1] Amended Complaint ¶ 19(g); Joint Appendix at 31. Notwithstanding the prescribed duties of the manufacturer outlined in the preceding paragraph, however, the majority concludes that it is within the DBS's discretion not to require even the submission of required test data, and to license the manufacture of a vaccine that has failed the required tests. This disregards the clear command of federal law:

> *Licenses . . . may be issued only upon a showing that* the establishment and *the products* for which a license is desired *meet standards*, designed to insure the continued safety, purity, and potency of such products, *prescribed in regulations*, and licenses for new products may be issued only upon a showing that they meet such standards.

42 U.S.C.A. § 262(d)(1) (West Supp. 1987) (emphasis added). Such statutory language creates, at a minimum,

[1] Thus, contrary to the majority's characterization, Berkovitz's position is *not* "simply that the FDA acted negligently." Maj. typescript at 25-26; *see, e.g.*, Brief for Appellees at 21 (DBS decided "to allow distribution to the public of a discrete live poliovirus vaccine [that] it *knew* exceeded explicit *regulatory* definitions of what is safe") (original emphasis); *id.* at 36 ("What must be accepted as true is that DBS knew that the vaccine lot in question exceeded the regulatory standard.").

a duty[2] to receive the showing that the vaccine manufacturer is, under the regulations, required to make to the government.[3] As the Ninth Circuit recognized last month,

> the Secretary may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted. *See* 42 U.S.C. § 262(d) [(1982)]; 21 C.F.R. § 630.10(b)(2) [(1987)]. Agency employees charged with enforcing poliovirus vaccine safety standards must require the submission of the test data. As to that there is no discretion.

Baker v. United States, 817 F.2d 560, 566 (9th Cir. 1987). The statute also creates a governmental duty not to license a manufacturer that has shown the government that its vaccine is defective. *See Loge v. United States*, 662 F.2d 1268, 1273 (8th Cir. 1981) ("The Secretary [of Health and Human Services] has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public."), *cert. denied*, 456 U.S. 944 (1982).

The majority believes that this statutory duty is not "different in substance" from the statutory duty of the Federal Aviation Administration ("FAA") that was analyzed by the Supreme Court in *Varig*. Maj. typescript at 23. This belief rests upon a misreading of *Varig* and

[2] That this section creates non-discretionary governmental duties is certainly implied by its subsection that prohibits "interfere[nce] with any officer, agent, or employee of the [Department of Health and Human] Service[s] in the performance of any *duty* imposed on him [or her] by this section or by regulations made by authority thereof." 42 U.S.C.A. § 262(e) (West 1982) (emphasis added).

[3] By contrast, this statute creates no DBS duty to receive what the manufacture is not, by regulation, obliged to send. *See, e.g.*, 21 C.F.R. § 610.2(a) (1987) (product "[s]amples . . . may at any time be required to be sent").

the federal laws that were considered therein. As the *Varig* Court noted, "[t]he FAA certification process is founded upon a relatively simple notion: *the duty to ensure* that an aircraft conforms to FAA safety regulations *lie with the manufacturer and operator*,[4] while the FAA retains the responsibility for policing compliance." [5] 467 U.S. at 816 (footnote and emphasis added). The FAA's legal duties are limited—as the majority's "illustrations" plainly show, *see* maj. typescript at 23-24—to making, or requiring the manufacturer to make, such tests "as the Secretary of Transportation deems reasonably necessary in the interest of safety," 49 U.S.C.A. § 1423(a)(2) (West Supp. 1987), and to "mak[ing] such inspection . . . as may be necessary to assure manufacture of each unit in conformity with [its type] certificate . . . ." 49 U.S.C.A. § 1423(b) (West Supp. 1987). These statutes are not commands at all. Rather, they amount to requests for the prudent exercise of agency discretion, and they are *truly* different in substance from the statute that *prohibits* vaccine licensure by the government whenever the requisite showing has not been made.

The majority's analysis distorts the discretionary function exception by extending its immunity to a government function that simply is not discretionary. "[F]ederal officials do not possess discretion to" violate federal law.[6]

---

[4] *Accord* Waymire v. United States, 629 F. Supp. 1396, 1402 (D. Kan. 1986) ("in *Varig*, the FAA made a policy decision . . . that the owner or manufacturer has the primary responsibility for inspecting the plane and for the complying with FAA regulations").

[5] The FAA's choice to fulfill this policing function by "review-[ing] the data for conformity purposes by conducting a 'spot check' of the manufacturer's work" is the discretionary function that was assessed by the *Varig Court*. 467 U.S. at 817.

[6] After carefully analyzing the Supreme Court's *Varig* and *Dalehite* opinions, Judge Bork recently noted that

> a decision cannot be shielded from liability if the decision-maker is acting without actual authority. A government official has no discretion to violate the binding laws, regulations or policies that define the extent of his [or her] official powers. An employee of the government acting beyond his [or her] authority is not exercising the sort of discretion the discretionary function exception was enacted to protect. This proposition is implied in *Varig* and *Dalehite*, and has been uniformly followed.

Red Lake Band of Chippewa Indians v. United States, 800 F.2d 1187, 1196 (D.C. Cir. 1986) (footnote omitted).

Pooler v. United States, 787 F.2d 868, 871 (3d Cir.), *cert. denied*, —— U.S. ——, 107 S. Ct. 175 (1986). Accordingly, I would affirm the judgment of the district court.

A True Copy:

Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

APPENDIX B

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 84-2893

KEVIN BERKOVITZ, a minor by his parent and natural guardians, ARTHUR BERKOVITZ his wife, DONNA BERKOVITZ and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right,

Plaintiffs,

v.

UNITED STATES OF AMERICA,

Defendant.

MEMORANDUM OPINION

DIAMOND, J.

The plaintiffs Arthur and Donna Berkovitz (hereafter, the Parent-Plaintiffs) in their own right and on behalf of their son, Kevin Berkovitz (hereafter, Minor-Plaintiff) initiated this suit alleging that the defendant negligently permitted the manufacture, sale, and licensure of Sabin Oral Poliomyelitis Vaccine (hereafter, SOPV), which, when administered to the Minor-Plaintiff by his physician, proximately caused the Minor-Plaintiff to sustain paralytic poliomyelitis.

Presently before the court is the defendant's motion to dismiss on the ground that it is immune from liability, and in the alternative, that the plaintiffs have failed to state a claim upon which relief may be granted. For the reasons given herein, the defendant's motion will be denied.

A. *IMMUNITY*

In accordance with the Public Health Services Act, 42 U.S.C. § 216(b), the Surgeon General promulgated regulations setting forth general and specific criteria for the manufacture of SOPV.[1] The requirements include the identification of various strains of attenuated polio virus, 21 C.F.R. § 630.10(b), the administration of the strain upon a population of at least one million people, 21 C.F.R. § 630.19(b)(2), and inoculation into rabits, mice, guinea pigs and various cultures, 21 C.F.R. § 630.16(a)(105). Unless the poliovirus strains and seed virus, conform to these tests, the Secretary of Health and Human Services cannot issue a license for the propagation, a manufacture and preparation or sale of the SOPV, 42 U.S.C. §§ 262(a) and (c).

In their complaint, the plaintiffs allege that the defendant was negligent in administering the applicable regulations. More specifically, the plaintiffs allege that Lederle Labs submitted to the defendant the requisite test results. However, the tests, and the results of the tests, did not comply with the regulations. Despite the non-compliable with regulations, the defendant negligently granted the original licensure to Lederle Labs and released the lot of the SOPV which was ingested by the Minor-Plaintiff.

The plaintiffs further allege that the defendant was negligent in failing to withdraw from the market the vaccine when the defendant knew or should have known that the vaccine failed to meet the requirements of the regulations; in failing to warn and take necessary pre-

---

[1] Initially, these regulations were codified under 42 C.F.R. § 73.110 *et seq.*, and were in effect when the original licensure was given to Lederle Labs, but the regulations were subsequently recodified under 21 C.F.R. § 630.10 *et seq.* Since the original regulations and the current regulations are essentially the same, for convenience, we will cite to the current regulations when discussing either set of regulations.

cautions; and in failing to require Lederle Laboratories to provide adequate warnings.

In its motion to dismiss, the defendant contends that it is immune from liability pursuant to the discretionary function exception of the Federal Tort Claims Act, 28 U.S.C. § 2680(a). The Federal Tort Claims Act (hereafter, FTCA) authorizes suits against the United States for personal injuries caused by the negligence of any employee of the United States Government while acting within the scope of his duties if a private person would be held liable to the claimant in accordance with the law of the place where the act or omission occurred. 28 U.S.C. § 1346(b). However, the FTCA does not authorize suits against the government if the alleged negligent acts arise from the execution of a statute or regulation or the performance of a discretionary function or duty. 28 U.S.C. § 2680(a). Accordingly, § 2680(a) exempts from liability: (1) those acts or omissions of government employees exercising due care in the carrying out statutes or regulations and (2) acts of discretion in the performance of governmental functions or duties whether or not such discretion is abused. *Delahite v. United States*, 346 U.S. 15 (1953).

The Supreme Court in *Delahite*, 346 U.S. 15, held that:

> [those discretionary acts or duties that cannot form the basis of a suit under the [FTCA] include more than the initiation of programs and activities. It also includes determinations made by executives or administrators in establishing plans, specifications, or schedules of operations. Where there is room for policy judgment and decisions there is discretion.

Delahite, 346 U.S. at 35-36. (footnote omitted). Hence, according to the court in *Delahite*, the discretionary function exception exempts policy judgment decisions.

The plaintiffs contend, citing *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974), that the approval of the

SOPV by the defendant contrary to the applicable regulation is not within the discretionary function exception to the FTCA. In *Griffin*, the plaintiff sustained personal injuries resulting from the ingestion of a SOPV which did not conform to the defendant's regulations. The Third Circuit concluded that the government was not immune from suit pursuant to the discretionary function exception. In reaching its decision, the court interpreted the *Delahite* definition of a discretionary function as decisions involving policy judgments as to the public interest. Applying this definition, the court found that the defendant's conduct was not immunized from judicial review as a discretionary function since the government employee's conduct in implementing agency regulations required only scientific evaluation and not the formulation of policy. *Griffin*, 500 F.2d at 1066.

The defendant denies that *Griffin* is controlling in light of the reasoning and holding in *United States v. VARIG Airlines*, 467 U.S. ——, 81 L.Ed.2d 660 (1984), and *General Public Utilities Corp. v. United States*, 745 F.2d 239 (3d Cir. 1984), *cert. denied*, —— U.S. ——, 106 S.Ct. 61 (1985), (hereafter *GPUC*). In particular the defendant contends that "the Third Circuit [in *GPUC*] made it clear that it read *VARIG* as broadly as it was written, namely, that the discretionary function exception exempts claims against federal agencies growing out of their regulatory activities." (Defendant's brief p. 22).

In *VARIG*, the court reaffirmed and further explained the *Delahite* holding. According to the Ninth Circuit, "VARIG points out [that] the exception applies when [an] agency makes a decision that is grounded in social, economic, and political policy [thereby preventing] the courts from deciding [by virtue of tort actions] the policy and political decisions that have been delegated to the agencies." *Begay v. United States*, 768 F.2d 1059, 1064 (9th Cir. 1985).

In *GPUC*, the plaintiffs, owners and operators of the Three Mile Island Nuclear facility brought pursuant to the FTCA a suit against the Nuclear Regulatory Commission (hereafter, NRC) for failing to exercise due care in discovering, analyzing and negligently approving the design and construction of the facility. In determining whether the alleged conduct of the NRC was within the protection of the discretionary function exception, the Third Circuit read the *VARIG* holding as suggesting that the discretionary function clause was to avoid the judicial second guessing of administrative decisions based upon social economic or political policy considerations. *GPUC*, 745 F.2d at 243. The court defined the proper inquiry as whether the challenge conduct is within the exception.

Having reviewed the statutory and regulatory scheme, the Court concluded that the NRC was protected by the discretionary function. According to the Court, the NRC was not performing a ministerial task but rendering a decision based upon technical and scientific evaluations coupled with concerns of public health and safety. The NRC, therefore, was acting in its role as regulator of private individual's conduct and that its decisions exemplify the underlying reason for the discretionary function exception—to prevent judicial second guessing.

In *GPUC*, the Third Circuit, in determining whether the failure of the nuclear regulatory commission to comply with the statutory requirements and regulations was within the discretionary function, instructed that *Griffin* should be read cautiously since the agency decision in *VARIG* rested on technical information. *GPUC*, *supra*. However, the court did not address the validity of *Griffin* in light of *VARIG*, *see GPUC*, 745 F.2d at 246 n.8.

While the parties have focused their attention on the validity of *Griffin*, we must apply *Griffin* to the case at bar. In *Poulis v. State Farm Fire & Casualty Co.*, 747 F.2d 863 (3d Cir. 1984), the court instructed:

> "It is the tradition of this court that the reported panel opinions are binding on the subsequent panels. Thus, no subsequent panel overrules a published opinion of a previous panel. The court en banc consideration is required to overrule a published opinion of this court."
>
> Internal Operating Procedures of the Court of Appeals for the Third Circuit, Chapter 8.C. If the courts of this court are bound by earlier panels, *a fortiorari* the district court judges are similarly bound. Recognition of hierarchical nature of the federal judiciary requires no less.

Poulis, 747 F.2d at 867. Accordingly, no matter how persuasive the arguments may be that *Griffin* is no longer valid, we are bound to apply the principles in *Griffin*. Thus, to the extent that the plaintiffs have alleged that the defendant was negligent in administering the applicable regulations, the allegations of the complaint are not within the discretionary function exception to the FTCA.

However, we believe that the defendant's alleged failure to warn and failure to withdraw the vaccine from the market are within the discretionary function exception. A decision to provide warnings to the public involves the balancing of the potential risk of harm with the public's need for such information. Similarly, a decision to withdraw from the market the vaccine requires an evaluation of the potential risk of harm. In the case before us, as in *GPUC*, these decisions encompass more than a scientific analysis of data, but an evaluation of public health and safety problems. Thus, a tort action challenging the defendant's decision not to warn or withdraw the product is the type of judicial second guessing which Congress sought to prevent by enacting the exception. *See VARIG*, 81 L.Ed.2d at 674.

Accordingly, for the aforementioned reasons we conclude that the defendant's negligent licensure and approval of the SOPV do not fall within the discretionary function exception and therefore, the defendant is not immune from liability. However, the defendant is immune from liability for its alleged failure to warn and withdraw the product.

B. *Failure to State a Claim*

The Federal Tort Claims Act provides that the law of the state in which the alleged acts occurred governs questions of liability. 28 U.S.C. § 3146; *Toole v. United States*, 588 F.2d 403 (3d Cir. 1978). In the instant matter, the plaintiffs allege, and the defendant does not dispute, that Pennsylvania law is controlling. In particular, the Minor-Plaintiff premises liability upon Pennsylvania's Good Samaritan doctrine.

Under Pennsylvania law, the Good Samaritan doctrine encompasses two theories of liability. The first theory of liability is set forth in § 323 of the Restatement of Torts which provides:

> One who undertakes . . . to render services to another which he should recognize as necessary for the protection of the other's person . . . is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking if (a) his failure to exercise such care increases the risk of harm or (b) the harm is suffered because of the other's reliance upon the undertaking.

Restatement (Second) of Torts § 323. The other theory is set forth in § 324A which provides:

> One who undertakes . . . to render services to another which he should recognize as necessary for the protection of a third person is subject to liability to the third person for physical harm resulting from

> his failure to exercise reasonable care . . . if (a) [such failure] increases the risk of harm or . . . (c) the harm is suffered because of the reliance of the other or third person upon the undertaking.

Restatement (Second) of Torts, § 324A.

Hence, in order to impose liability under these sections the negligently performed acts must increase the risk of harm or the injured plaintiff must rely upon the defendant's performing the services he has undertaken to render. *Feld v. Meriam*, —— Pa. ——, 485 A.2d 742 (1984). The failure to plead increase risk of harm or reliance by the plaintiff upon the defendant's acts has resulted in the dismissal of the complaint. *See, e.g., Patentas v. United States*, 687 F.2d 707 (3d Cir. 1982).

In the case at bar, the Minor-Plaintiff properly averred that the defendant "undertook to render services" by assuming the obligation to monitor and test SOPV before issuing the license for the manufacture or sale of the substance. Even though the Minor-Plaintiff failed to allege that the defendant's failure to exercise reasonable care increased the risk of harm or such harm was due to the Minor-Plaintiff's reliance upon the defendant, the Minor-Plaintiff's reliance upon the defendant, the Minor-Plaintiff has averred in his response to this court's order of October 30, 1985, that he intends to prove that the defendant's conduct increased the risk that he would contract poliomyelitis and that the Parent-Plaintiffs relied upon the defendant's approval of the drug when they permitted the Minor-Plaintiff to consume the vaccine.

Despite the plaintiffs' failure to plead that the defendant's conduct increased the risk of harm to the Minor-Plaintiff or such harm was due to his reliance upon the defendant's undertaking of licensing the SOPV, we will not dismiss the complaint. In *Patentas*, 687 F.2d 707, the court dismissed the complaint but noted that "the

[plaintiffs did not make] adequate allegations or proof of increased risk of harm." *Id.* at 717. Since the Minor-Plaintiff has made an offer of proof of increased risk of harm, we will deny defendant's motion to dismiss and grant the plaintiffs leave to amend their complaint.

An appropriate order will follow.

/s/ Justice Diamond
United States District Judge

Date: April 30, 1986

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

Civil Action No. 84-2893

KEVIN BERKOVITZ, a minor by his parents and natural guardians, ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right,

Plaintiffs,

v.

UNITED STATES OF AMERICA,

Defendant.

ORDER OF COURT

AND NOW, this 30th day of April, 1986, for the reasons stated in the memorandum opinion filed this date in the above-captioned action, IT IS ORDERED that the plaintiffs are granted leave to amend their complaint; and,

IT IS FURTHER ORDERED that defendant's motion to dismiss be, and the same hereby is, denied.

/s/ Justice Diamond
United States District Judge

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IT IS FURTHER ORDERED that defendant's motion to dismiss be, and the same hereby is, denied.

/s/ Justice Diamond
United States District Judge

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APPENDIX C

STATUTES AND REGULATIONS

§ 262 Regulation of biological products

* * * *

Regulations governing licenses

(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

* * * *

§ 601.20 Product licenses; issuance and conditions.

(a) *Examination—compliance with standards.* A product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations in this subchapter: *Provided*, That no product license shall be issued except upon a determination that the establishment standards prescribed in the regulations contained in this subchapter, applicable to the manufacture of such product.

* * * *

(2)

Supreme Court, U.S.
FILED
DEC 11 1987
JOSEPH F. SPANIOL, JR.
CLERK

No. 87-498

In the Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

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QUESTION PRESENTED

Whether the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. 2680(a), bars petitioners' claims that the government was negligent in its 1963 decision to license Lederle Laboratories' Sabin oral polio vaccine and in its subsequent approval of the release of a specific lot of that vaccine.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	1
Statement	1
Argument	4
Conclusion	9

TABLE OF AUTHORITIES

Cases:

Bacon v. *United States*, 810 F.2d 827 (8th Cir. 1987)	7
Baker v. *United States*, 817 F.2d 560 (9th Cir. 1987)	4, 5, 9
Barnson v. *United States*, 816 F.2d 549 (10th Cir. 1987)	7
Baxley v. *United States*, 767 F.2d 1095 (4th Cir. 1985)	7
Begay v. *United States*, 768 F.2d 1059 (9th Cir. 1985)	7
Cisco v. *United States*, 768 F.2d 788 (7th Cir. 1985)	7
Collins v. *United States*, 783 F.2d 1225 (5th Cir. 1986)	6
Cunningham v. *United States*, 786 F.2d 1445 (9th Cir. 1986)	7
Feyers v. *United States*, 749 F.2d 1222 (6th Cir. 1984), cert. denied, 471 U.S. 1125 (1985)	7
General Public Utilities Corp. v. *United States*, 745 F.2d 239 (3d Cir. 1984), cert. denied, 469 U.S. 1228 (1985)	7-8
Griffin v. *United States*, 500 F.2d 1059 (3d Cir. 1974)	3, 5
Hylin v. *United States*, 755 F.2d 551 (7th Cir. 1985)	7
Loge v. *United States*, 662 F.2d 1268 (8th Cir. 1981), cert. denied, 456 U.S. 944 (1982)	5
McMichael v. *United States*, 751 F.2d 303 (8th Cir. 1985)	6
Merklin v. *United States*, 788 F.2d 172 (3d Cir. 1986)	7
Natural Gas Pipeline Co. v. *United States*, 742 F.2d 502 (9th Cir. 1984)	8
Russell v. *United States*, 763 F.2d 786 (10th Cir. 1985)	7
Shuman v. *United States*, 765 F.2d 283 (1st Cir. 1985)	7
United States, v. *S.A. Empresa Aerea De Viacao Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984)	3, 4, 6, 9

Statutes and regulations: Page

Federal Tort Claims Act, 28 U.S.C. 2680(a) 2
28 U.S.C. 1292(b) 3
21 C.F.R. 630.10(b) 6
42 C.F.R. 73.110(b) (1963) 6

In the Supreme Court of the United States

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-27a) is reported at 822 F.2d 1322. The opinion of the district court (Pet. App. 28a-36a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on June 30, 1987. The petition for a writ of certiorari was filed on September 25, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioner Kevan Berkovitz contracted polio from Orimune, a Sabin oral polio vaccine manufactured by Lederle Laboratories. Berkovitz, joined by his parents as guardians, filed suit in federal district court alleging that the United States is liable for his injuries under the Federal Tort Claims Act (FTCA) because the government was negligent in licensing Orimune on June 25, 1963, and

because the Food and Drug Administration (FDA) was negligent in releasing the specific lot of vaccine from which Berkovitz received his dose on May 10, 1979.[1] As to the first claim, petitioners allege that the Division of Biologic Standards (DBS), at that time part of the National Institutes of Health, issued a license for Lederle's Sabin poliovirus strain when it had not been tested in accordance with DBS' own regulations, and that DBS failed to require Lederle to show that a particular "seed virus" had been subjected to all required testing and had complied with all regulatory standards. Pet. 4; Pet. App. 4a-5a. On the second issue, petitioners claim that the Bureau of Biologics of the FDA improperly issued a lot release approval, permitting the vaccine containing Berkovitz's dose to be distributed to the public, despite the fact that the virus in the vaccine had been tested and found to exceed the standards for neurovirulence set forth in regulations applicable to live polio vaccines. Pet. 5; Pet. App. 4a-5a.[2]

2. The government moved to dismiss the suit as barred by the discretionary function exception to liability under the FTCA, 28 U.S.C. 2680(a).[3] The district court agreed

[1] Petitioners also claimed in district court that the United States was negligent in failing to withdraw the vaccine from the market and in failing to require the manufacturer to provide adequate warnings. These allegations were dismissed in the district court as barred by the FTCA's "discretionary function" exception, and petitioners conceded the propriety of that dismissal on appeal (Pet. App. 6a n.4). No further review on those issues has been sought.

[2] Since the case was disposed of on the government's motion to dismiss in lieu of an answer, the government has as yet had no occasion to assert its vigorous disagreement with petitioners' factual allegations, which for purposes of this motion must be taken as true.

[3] Section 2680(a) provides that the FTCA does not apply to "[a]ny claim based upon • • • the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused."

that the government was immune from two of petitioners' original claims,[4] but nonetheless concluded that both the licensing of the vaccine and the release of the specific vaccine lot were not "discretionary function[s]" within the meaning of the FTCA. The district court noted that the Third Circuit had already held in *Griffin* v. *United States*, 500 F.2d 1059 (1974), that negligent licensing and release of a polio vaccine were not discretionary functions. The government maintained in its motion to dismiss that *Griffin* had been effectively overruled by this Court's decision in *United States* v. *S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984). The district court declined to consider the effect of *Varig Airlines*, however, noting that, as a reported decision of the Third Circuit, *Griffin* was binding on the district courts in that circuit "no matter how persuasive the arguments may be that *Griffin* is no longer valid" (Pet. App. 33a).

3. At the government's request, the district court certified its decision for immediate appeal to the Third Circuit pursuant to 28 U.S.C. 1292(b). Although rejecting the government's argument that the discretionary function exception applies to all claims arising from the regulatory activities of federal agencies (Pet. App. 12a-15a), the court of appeals reversed in a divided opinion. Concluding that it "need not treat separately the licensing claim and the lot release claim" (*id.* at 15a), the court proceeded to analyze the question whether the government had a nondiscretionary duty to ensure that Lederle followed regulatory standards in the production and distribution of the Sabin polio vaccine (*ibid.*). The court of appeals canvassed the applicable regulations and noted that, while they required the manufacturer to perform certain tests and submit qualifying results to the government, they did not require the government to do anything (*id.* at 18a-22a). The court

[4] See n.1, *supra*.

concluded that, as in *Varig Airlines,* the onus was on the manufacturer to comply with applicable safety standards, while the role of the government agency was " 'merely to police the conduct of private individuals by monitoring their compliance with [the applicable] regulations' " (*id.* at 22a (quoting 467 U.S. at 815)). Because "neither the statute nor the regulations mandate the FDA's choice of how to secure Lederle's compliance" (Pet. App. 22a), the court concluded that the discretionary function exception bars suit for alleged negligence in the government's performance of that role.[5]

ARGUMENT

In our view, the decision of the court of appeals is correct. There is, however, a direct conflict between this decision and a recent decision by the Ninth Circuit. Furthermore, that direct conflict is symptomatic of a broader post-*Varig Airlines* disharmony among the courts of appeals concerning the extent to which the negligent execution of a safety-related regulatory program is subject to suit under the FTCA. Finally, the question presented in this case is important and its resolution may have far-reaching consequences upon the future availability of life-saving vaccines. Accordingly, we agree with petitioners that the Court should grant certiorari in this case.

1. On May 18, 1987, just over a month before the court of appeals' decision in this case, the Ninth Circuit held that the discretionary function exception did not apply to the government's 1963 decision to license the Lederle oral polio vaccine. *Baker* v. *United States,* 817 F.2d 560, 565-566 (1987). The plaintiff in *Baker* alleged that DBS

[5] Judge Higginbotham dissented (Pet. App. 23a-27a), concluding that the government has no discretion to issue licenses for vaccines that have not been tested and found to meet the requirements set forth in the regulations.

negligently violated its own regulations when it failed to require submission of test data before making its licensing decision. The Ninth Circuit relied in part on the pre-*Varig Airlines* cases of *Griffin* v. *United States, supra,* and *Loge* v. *United States,* 662 F.2d 1268 (8th Cir. 1981), cert. denied, 456 U.S. 944 (1982), and distinguished *Varig Airlines,* where "the mandatory regulations governed the conduct of the airline, not the government" (817 F.2d at 565-566). It said that in this case, by contrast, the agency "may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted," and that the agency thus has a mandatory duty to require the submission of those data (*id.* at 566). The court was unwilling to apply the discretionary function exception to the plaintiff's allegations of "a negligent failure to obey a mandatory regulatory command" (*ibid.*). The government's petition for rehearing with a suggestion of rehearing en banc was denied by the Ninth Circuit on October 15, 1987.

There is, thus, a direct conflict between the Third Circuit's holding that the FDA's Sabin vaccine licensing decision was a discretionary function, and the Ninth Circuit's decision in *Baker* that it was not.[6] The government will shortly file a petition for a writ of certiorari in the *Baker* case. We suggest that the Court grant certiorari in this case, and hold *Baker* pending a decision on the merits here.[7]

[6] In the present case, the court of appeals noted the *Baker* decision and stated that "Berkovitz's complaint can be read as alleging a similar failure to require submission of test data." The court of appeals expressly declined to follow the Ninth Circuit panel's determination on this issue, stating (Pet. App. 18a n.6):

> We do not agree [with the *Baker* determination], however, that the FDA is under a duty to require submission of test data. Rather, the duty to submit test data rests with the manufacturer. *See* 21 C.F.R. §§ 601.2, 610.1, 630.10(b)(4)(1987).

[7] We agree with the Third Circuit that the additional allegation that the FDA was negligent in releasing the lot of vaccine containing peti-

2. This direct conflict between the Third and Ninth Circuits is part of a larger confusion among the courts of appeals as to the proper application of this Court's decision in *Varig Airlines*. In *Varig Airlines*, the Court held that the FAA's program of spot-checking compliance with safety standards, with the primary burden placed on the manufacturer to ensure compliance, "falls squarely within the discretionary function exception" (467 U.S. at 820). "The FAA," the Court noted, "has a statutory duty to *promote* safety in air transportation, not to insure it" (*id.* at 821 (emphasis in original)). Two circuits, however, in cases decided after *Varig Airlines*, nonetheless have imposed liability on the government for negligence in conducting safety compliance checks. See *Collins* v. *United States*, 783 F.2d 1225 (5th Cir. 1986) (decision by Mine Safety and Health Administration to rescind an "Imminent Danger Order" and not to reclassify mine as "gassy" after inspection revealed high methane levels); *McMichael* v. *United States*, 751 F.2d 303 (8th Cir. 1985) (failure of Defense Department inspectors to enforce safety requirements on defense contractor). Both courts distinguished *Varig Airlines* because the inspectors in question had no discretion not "to enforce the detected violations of the safety requirements" (*McMichael*, 751 F.2d at 307; see *Collins*, 783 F.2d at 1230-1231).

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tioner Berkovitz's dose does not materially alter the analysis for purposes of the discretionary function exception, since the regulations which governed that decision, 21 C.F.R. 630.10(b), are almost identical to those in effect when the original licensing decision was made. 42 C.F.R. 73.110(b) (1963).

We note, however, that this additional allegation concerning the lot release decision was not present in *Baker*. Should the Court so desire, it could thus limit its consideration to the precise issue on which there is a conflict – the applicability of the discretionary function exception to the 1963 vaccine licensing decision – either by granting the petition in *Baker* and holding this case pending its resolution or by limiting the grant of certiorari here.

Most courts, by contrast (including a different panel of the Eighth Circuit), have heeded this Court's injunction not to turn agency efforts to enhance safety into government insurance of regulated industries. See, *e.g.*, *Barnson* v. *United States*, 816 F.2d 549 (10th Cir. 1987) (alleged failure of U.S. Public Health Service and AEC to warn uranium miners of, and protect them against, radiation hazards); *Bacon* v. *United States*, 810 F.2d 827 (8th Cir. 1987) (alleged failure of HUD and EPA to warn of dioxin levels during repair of roads at Times Beach under federal block grant); *Merklin* v. *United States*, 788 F.2d 172 (3d Cir. 1986) (AEC inspectors' alleged failure to warn uranium processing plant employees of health hazards discovered during AEC inspections); *Cunningham* v. *United States*, 786 F.2d 1445 (9th Cir. 1986) (alleged failure of OSHA to exercise reasonable care in conducting plant inspections); *Begay* v. *United States*, 768 F.2d 1059 (9th Cir. 1985) (alleged failure by federal agencies to warn of dangers of uranium mining); *Cisco* v. *United States*, 768 F.2d 788 (7th Cir. 1985) (EPA's alleged failure to warn that dirt contaminated with dioxin had been used in residential land fill); *Baxley* v. *United States*, 767 F.2d 1095 (4th Cir. 1985) (FAA's allegedly negligent decision not to regulate or inspect ultralite aircraft); *Shuman* v. *United States*, 765 F.2d 283 (1st Cir. 1985) (alleged negligence by Navy in not controlling use and handling of asbestos by contractor); *Russell* v. *United States*, 763 F.2d 786 (10th Cir. 1985) (alleged negligence by MSHA in inspecting coal mine); *Hylin* v. *United States*, 755 F.2d 551 (7th Cir. 1985) (mine inspectors' alleged failure fully to inspect clay mine); *Feyers* v. *United States*, 749 F.2d 1222 (6th Cir. 1984) (Army's allegedly negligent failure to inspect contractor's operation of government-owned railyard), cert. denied, 471 U.S. 1125 (1985); *General Public Utilities Corp.* v. *United States*, 745 F.2d 239 (3d Cir. 1984) (NRC's alleged failure to warn of possible

equipment defects at Three Mile Island nuclear facility), cert. denied, 469 U.S. 1228 (1985); *Natural Gas Pipeline Co.* v. *United States,* 742 F.2d 502 (9th Cir. 1984) (alleged negligence in FAA inspection and issuance of certificates for aircraft).

Despite the weight of authority in the government's favor, a conflict meriting this Court's attention exists on the question of whether an agency's alleged failure to follow its own regulations in regulating the safety of a given industry can give rise to liability under the FTCA. The decisions in *Collins, McMichael,* and now *Baker* clearly attest to the need for further clarification by this Court of its decision in *Varig Airlines.* The current case provides an appropriate vehicle for that clarification.

3. An additional reason to grant certiorari is the importance of the particular question presented here. In 1963, the government made a considered decision, based on detailed test results from the Soviet Union and elsewhere, to approve use of the Sabin oral polio vaccine to combat the still widespread problem of polio. That vaccine is now administered routinely to virtually all children in the United States, and has all but eliminated incidence of that once-dreaded disease. Each year, however, a small number of persons suffer adverse reactions to the Sabin oral polio vaccine. The *Baker* decision permits those persons to seek damages from the United States based on alleged negligence in the government's decision to approve the vaccine. In our view, such tort suits against the government pose a serious threat to the continued availability of this life-saving vaccine. If a court were to conclude that the government was indeed negligent because it failed to follow its own regulations in licensing the vaccine in 1963, thereby rendering the government liable for all damages resulting from it, the government—if it did not want to become a complete insurer of the vaccine—might have to order its withdrawal pending a new licensing proceeding.

The discretionary function exception was designed to avoid just such dilemmas. *Baker* simply cannot be squared with this Court's holding in *Varig Airlines,* 467 U.S. at 813-814, that "whatever else the discretionary function exception may include, it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals."

The Ninth Circuit's decision also has broad implications for the availability of new drugs and vaccines in the United States, all of which must be approved by the FDA. The court stated, without explanation, that "the [discretionary function] exception should be applied cautiously in the field of drug and vaccine testing" (*Baker,* 817 F.2d at 565). To the contrary, nowhere is that exception more appropriate than here, where the government seeks to walk a razor's edge between overcaution and undue haste, while thousands of lives hang in the balance. This is precisely the sort of policy decision that Congress did not want to subject to "judicial 'second-guessing' * * * through the medium of an action in tort" (*Varig Airlines,* 467 U.S. at 814).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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DECEMBER 1987

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Supreme Court, U.S.
FILED
FEB 25 1988
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No. 87-498

IN THE
Supreme Court of the United States
OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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JOINT APPENDIX

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PETITION FOR CERTIORARI FILED SEPTEMBER 25, 1987
CERTIORARI GRANTED JANUARY 11, 1988

JOINT APPENDIX
INDEX

Docket Entries	Page
District Court	1
Court of Appeals	6
Complaint	8
Motion to Dismiss	18
Judgment of Court of Appeals	20

NOTICE

The following opinions and orders have been omitted in printing this Joint Appendix because they appear on the following pages in the printed Appendix to the Petition for a Writ of Certiorari, which is incorporated herein by reference.

	Page
Order and Opinion of Court of Appeals, June 30, 1986	Pet. App. 1a
Order and Opinion of District Court, April 30, 1986	Pet. App. 28a

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

Civil Action No. 84-2893

KEVAN BERKOVITZ, a minor, by his parents and natural guardians, ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ, and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right,

Plaintiffs

v.

UNITED STATES OF AMERICA,

Defendants

RELEVANT DOCKET ENTRIES

DATE	NR.	PROCEEDINGS
1984		
Dec 5	1	Complaint Filed.
Dec 5	—	Summons Issued
1985		
Feb 11	2	Motion for Enlargement of time to File answer filed by the Deft with a Proposed order.
Feb 19	W/2	Order of Court entered Feb 19 1985 directing that deft U.S.A. shall have until Feb 26 1985 within which to file an Answer (Mansmann J)
Feb 25	3	Deft United States of Americas Motion to Dismiss filed with a proposed order.
Feb 28	4	Order of Court entered Feb 27 1985 directing that the Deft U.S.A. having filed a motion to Dismiss together with a memorandum in sup-

DATE	NR.	PROCEEDINGS
1985		
		port, IT is Ordered that Pltfs file a response to the Above motion together with memorandum in support on or before Mar 11 1985 (Mansmann J)
May 6	—	The above case is Re Assigned to Judge Diamond.
Jun 26	5	Order of Court fixing Pre Trial Procedure entered Jun 25 1985 directing that all discovery be Completed by Oct 23 1985 (Diamond J)
Jul 12	6	Motion to Stay Discovery and Vacate June 25 1985 order of the Court fixing pre trial procedure filed by the deft U.S.A.
Sept 10	7	Memorandum Order entered Sept 10 1985 directing that deft having filed a motion to stay discovery and vacate the Jun 25 1985 order of this court fixing pre trial procedure and brief, It is ordered that since there appears to be a legal question raised by the motion that may result in an entire dismissal of the action the court will make an exception to its standard pre trial order and Grant the motion to Stay (Diamond J)
Oct 30	8	Order of Court entered Oct 30 1985 directing that the Pltfs in the above case indicate to the Court within 10 days from the date of this order whether pltfs intend to prove that the alleged negligent conduct of the Deft either increased the risk of harm to the Pltf Kevin Berkovitz or that the alleged harm suffered by Pltf Kevin Berkovitz was due to reliance upon the Defts Conduct (Diamond J)
Nov 1	9	Response to Order of Court of Oct 30 1985 filed.

DATE	NR.	PROCEEDINGS
1986		
Feb. 12	10	Supplement to Defendant J. A's motion to dismiss or in the alternative for summary judgment filed
Mar 3	11	Pltfs Answer to the Supplement to Defts United States of America Motion to Dismiss or in the alternative for Summary Judgment filed.
Apr 30	12	Memorandum Opinion Filed (Diamond J)
Apr 30	13	Order of Court entered Apr 30 1986 directing thta the Pltfs are Granted Leave to Amend their Complaint and It is further ordered that Defts Motion to Dismiss is Denied (Diamond J)
May 8	14	Order of Court entered May 7 1986 fixing pre trial procedure and all Discovery be Completed by July 7 1986
May 9	15	ANSWER Filed by the Deft U.S.A.
Jun 5	16	United States Motion for Reconsideration or in the Alternative for Certification for interlocutory Appeal filed with a Proposed order.
Jun 16	17	Pltf's motion to extend time for discovery and compliance with pretrial deadlines in view of deft's failure to respond to existing discovery and in view of deft's motion for reconsideration or, in alternative, certification filed.
June 16	18	Pltf's opposition to motion of U.S. for reconsideration and statement of no opposition to motion of U.S. for certification for interlocutory appeal filed.
June 16	19	Amended complaint filed by pltf. amending body of pltf

DATE	NR.	PROCEEDINGS
1986		
June 19	W-16	Order dated 6/18/86 entered on motion filed 6/5/86 grating deft's motion for reconsideration or alternatively, for certification for interlocutory appeal and that upon reconsideration this court reaffirms its memor. opinion dated 4/30/86 and hereby incorporates its ruling herein by reference and that this order including the memo. ruling incorporated by reference herein, involves a controlling question of law to which there is substantial ground for difference of opinion and that immediate appeal may materially advance the ultimate determination of this litigation and it is ordered that its incorporated Memo. order of 4/30/86 is hereby certified to U.S. Court of Appeals pursuant to 28 U.S.C. 1292(b) and further ordered that defts motion for reconsideration or alternatively, for certification for interlocutory appeal is granted with respect to certification for interlocutory appeal (Diamond, J.)
Jul 9	20	Stipulation to stay discovery during the pendency appeal filed with a proposed order.
Jul 14	W/20	Order of Court entered Jul 14 1986 directing that Discovery shall be Stayed pending acceptance by the U.S. Court of Appeals of the Interlocutory Appeal of the instant Action and If the Third Circuit accepts the Interlocutory appeal of the above action Discovery shall be stayed pending the resolution of the appeal and if the Third Circuit declines to accept the Interlocutory appeal of the above action, the parties agree to confer regarding the Establishment of a discovery schedule (Diamond J)

DATE	NR.	PROCEEDINGS
1986		
Jul 21	21	Certified copy of Order dated Jul 17 1986 received from the U.S. Court of Appeals directing that Petition for Permission to take and Interlocutory Appeal, in which it states that Pltfs did not oppose the Motion for Certification of an Interlocutory appeal in the District Court, and the Foregoing Motion is Granted (Adams J)
Jul 21	—	Letter and Copy of June 18 1986 order mailed to the U.S. Court of Appeals with Certified copy of the Docket Sheet. No filing fee on the Interlocutory Appeal, Filed by the U.S.A. (No Court Reporter) Notice to Counsel of Record.
July 23		TPO mailed Atty Rupert Mitsch, Dept. of Justice, appellant
Jul 28	22	Transcript Purchase order filed by the U.S.A. and Indicating that a transcript is Unnecessary for appeal purposes.
Jul 28	—	The above case is Complete for Appeal Purposes, and Three Copies of the Docket Sheet mailed to the U.S. Court of Appeals, One Certified
Jul 30	—	Notice received from the U.S. Court of Appeals advising that the above case was Docketed at (86-3444)
Aug 1	—	Receip received from the U.S. Court of Appeals of the Certified List in Lieu of the Record.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Docket No. 86-3444

KEVAN BERKOVITZ, a minor by his parents and natural guardians, ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ, and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right

v.

UNITED STATES OF AMERICA,
Appellant

RELEVANT DOCKET ENTRIES

DATE	FILINGS--PROCEEDINGS
1986	
July 17	NOA FILED
July 28	DOCKETED:
1987	
Jan. 14	Ltr. dtd 1-9-87, from Ellen R. Viakley, Esq., cnsel for aplees, sent for Ct's info, filed. (ms)
Feb. 19	Ltr dtd 2-18-87, from aplts' cnsel, rec'd for Ct.'s info. (ms)
Feb. 19	At oral argmt. cnsl was directed to arrange for transcript of oral argmt. for the Ct. (ab)
Feb. 19	ARGUED/SUBMITTED
March 4	Transcript of oral argument rec'd for info of ct (as)
May 26	Let dtd 5-22-87 from aplee with enc. pursuant to Rule 28(j) F.R.A.P., rec'd for Ct's info. (ms)

DATE	FILINGS—PROCEEDINGS
1987	
June 19	Letter dated 6/18/87, from Nanette R. Everson, esq., counsel for appellant, pursuant to Rule 28(j), F.R.A.P. (mgp)
June 30	OPINION
	JUDGMENT reversing & remanding to DC with dir. to grant government's summary judgment mot. csts txd agnst appellee (sa)
July 14	PET. FOR REHG. by appellee w/serv. (sa)
July 22	Denied. Judges Higginbotham, Becker & Mansmann would grant rehg.
July 28	Mot. by appellee to stay the mandate to & including Aug. 28, 1987, w/serv. filed (sa)
July 30	Order (Sloviter, Cir. Judge) granting the above mot. filed (sa)
Aug 13	Mot. by appee. for further stay of mandate to & incldg. 9/28/87 w/serv. fid. (sa)
Aug 14	Order (Sloviter) granting above mot. fld. (sa)

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA

Civil Action No. 84-2893

KEVAN BERKOVITZ, a minor, by his parents and natural guardians, ARTHUR BERKOVITZ and DONNA BERKOVITZ, his wife; and ARTHUR BERKOVITZ and DONNA BERKOVITZ in their own rights,

Plaintiffs

vs.

UNITED STATES OF AMERICA,

Defendant.

COMPLAINT

First Count

Kevan Berkovitz, a minor, Plaintiff vs. United States of America, Defendant.

1. Minor Plaintiff, Kevan Berkovitz is resident of Belle Vernon, Washington County, Pennsylvania, where he resides with his parents, Arthur Berkovitz and Donna Berkovitz, the other Plaintiffs herein.

2. Defendant, United States of America, is a sovereign and is subject to suit under the Federal Tort Claims Act, 28 U.S.C. Section 1346 *et seq.*, and 28 U.S.C. Section 2680 *et seq.*

3. On or about May 10, 1979, minor Plaintiff was administered Orimune, the Sabin Oral Poliomyelitis Vaccine (hereinafter "SOPV"), manufactured by Lederle Laboratories, a division of the American Cyanamid Company (hereinafter "Lederle Laboratories"). Said vaccine was administered to minor Plaintiff by his pediatrician in North Charleroi, Pennsylvania.

4. On or about June 4, 1979, as a result of the administration of the said vaccine, minor Plaintiff sustained paralytic poliomyelitis and other injuries more fully described hereafter.

5. Defendant, through its agency, the Communicable Disease Center, Atlanta, Georgia, and its agents, servants and employees, determined that minor Plaintiff's paralytic poliomyelitis was a result of the SOPV administered to minor Plaintiff, and further, that minor Plaintiff had suffered a Type 3 vaccine-associated case of poliomyelitis.

6. Prior to minor Plaintiff being administered Orimune, Defendant, pursuant to its duty, had promulgated rules and regulations for the manufacture, sale and licensure of SOPV. Said rules and regulations were published in the Federal Register and had the force of law.

7. Under the rules and regulations promulgated, Defendant had the further duty to assure that the SOPV would meet the requirements of the regulations in order to assure the safety, purity and potency of the said product to recipients such as minor Plaintiff and to persons coming in contact with recipients.

8. These initial regulations were contained in the code of federal regulations at 42 C.F.R., 73.110 *et seq.* These regulations were promulgated March 25, 1961, to become effective April 24, 1961.

9. On March 16, 1968, parts of the aforementioned regulations were modified and published in the Federal Register, Volume 33, No. 53. Thereafter, the rules and regulations were again modified and are contained in 21 C.F.R., 630.10 *et seq.*

10. Defendant was and is charged with the responsibility of assuring compliance with the said regulations

by manufacturers of SOPV, including, but not limited to, Lederle Laboratories.

11. As a result of the negligence of Defendant, by and through its agents, servants and employees, minor Plaintiff sustained paralytic poliomyelitis following the administration of Orimune in the office of minor Plaintiff's pediatrician on May 10, 1979.

12. The initial symptoms of the vaccine-associated illness suffered by minor Plaintiff as a result of the negligence of Defendant were first manifested on June 4, 1979.

13. On May 8, 1981, notice of claim was sent to Defendants' Department of Health and Human Services, Washington, D.C. 20201, in accordance with the Federal Tort Claims Act, 28 U.S.C. Section 1346, *et seq.*, 28 U.S.C. Section 2680.

14. More than six months has passed since the date of said notice of claim and no formal rejection of the notice has been made by the Department of Health and Human Services or any other authorized governmental agency.

15. The duty to administer, regulate and supervise the manufacture, licensure, sale and distribution of SOPV and the enforcement of the regulations promulgated for the above purpose was initially the responsibility of Defendants' National Institutes of Health, Division of Biologic Standards. This responsibility was thereafter transferred to Defendants' Food and Drug Administration, Bureau of Biologics. All of these agencies are or were agencies of Defendant's Department of Health and Human Services, previously known as The Department of Health, Education and Welfare.

16. At the time of the original licensure of SOPV, the division responsible for the granting of such licensure was Defendant's Division of Biologic Standards.

17. The Division of Biologic Standards was negligent in some or all of the following particulars:

(a) In failing to assure that Lederle Laboratories, the manufacturer of Orimune complied with applicable regulations, including, but not limited to: 42 C.F.R. 73.110(b)(2); 42 C.F.R. 73.110(b)(4); 42 C.F.R. 73.110(b)(5); 42 C.F.R. 73.114(b)(1); 42 C.F.R. 73.114(b)(1)(i)(ii)(iii); 42 C.F.R. 73.114(b)(3); 42 C.F.R. 73.117; 42 C.F.R. 73.116(a); 42 C.F.R. 73.116(c);

(b) In improperly relying upon studies performed by the Union of Soviet Socialist Republics to form the basis of the testing for the licensing of said vaccine under 42 C.F.R. 73.110, inasmuch as: The vaccine administered to the Russian population was a vaccine different than that licensed and produced by the United States of America; the vaccine administered to the Russian population was administered in a different dosage than that required under 42 C.F.R. 73.110, *et seq.*; the population receiving said vaccine was not demonstrated to be susceptible to poliomyelitis by blood tests, stool examinations or other appropriate methods; the Russian studies did not include the number of susceptible persons required by the regulations; and the epidemiologic surveillance of neurological illness was not adequate according to standards required by 42 C.F.R. 73.110 *et seq.*;

(c) In failing to prevent the said SOPV from being licensed in the United States, when Defendant, through its Communicable Disease Center, through its Division of Biologic Standards and through its Surgeon General's Office, knew that prior to the approval of the licensure for Lederle Laboratories cases of paralytic poliomyelitis were occurring with SOPV administered in Russia in such a number as to fail

the requirements necessary for licensure under 42 C.F.R. 73.110(b)(2);

(d) In licensing Lederle Laboratories for the manufacture of SOPV in the absence of the manufacturer's demonstrated compliance with the applicable regulation 42 C.F.R. 73.110(b)(4), which required that the seed virus utilized for the manufacture of SOPV was to be tested intrathalamically, intraspinally and intramuscularly, in conjunction with a comparative analysis with the applicable reference strain;

(e) In permitting the distribution of trivalent vaccine administered to minor Plaintiff when the seeds, from which the monovalent pools utilized in said trivalent vaccine were manufactured, had not been tested in accordance with the requirements of 42 C.F.R. 73.110(b)(4);

(f) In licensing Lederle Laboratories for the manufacture of SOPV in contravention of the applicable regulation, 42 C.F.R. 73.110(b)(2), requiring the manufacturer to furnish studies indicating that 100,000 people, demonstrated to be susceptible by blood tests, stool examinations and other appropriate methods with regard to Type 1, Type 2 and Type 3 SOPV and/or trivalent SOPV, had been administered said vaccine under circumstances where adequate epidemiological surveillance of neurological illness had been maintained;

(g) In licensing Lederle Laboratories for the manufacture of SOPV when the five original licensing monovalent pools and trivalent lots, submitted to qualify SOPV for licensure, had failed neurovirulence tests as to certain Type 1 and Type 3 monovalent virus pools;

(h) In failing to enforce regulation 42 C.F.R. 73.110(b)(5) which required requalification of the

seed virus in accordance with 42 C.F.R. 73.110(b)(4), when there was a change in the neurovirulence of the production virus used by the manufacturer;

(i) In generally failing to require Lederle Laboratories to test the seeds for each type of SOPV in accordance with applicable regulations or to require Lederle Laboratories to submit evidence of such tests;

(j) In otherwise being negligent under the circumstances.

18. In or about 1972 and thereafter, enforcement of the regulations governing the licensing, manufacture and distribution of SOPV became the designated responsibility of the Bureau of Biologics, Food and Drug Administration.

19. The Bureau of Biologics was negligent in some or all of the following particulars:

(a) In violating the rules and regulations governing the licensure, manufacture and distribution of SOPV at 42 C.F.R. 73.110 *et seq.* and 21 C.F.R. 630.10 *et. seq.*;

(b) In undertaking responsibility to test for safety various lots of SOPV Type 1, Type 2 and Type 3, and then in releasing said lots even though testing by Defendant disclosed that the lots failed to meet the necessary requirements for safety, purity and potency, which lots were distributed to individuals, including, but not limited to, minor Plaintiff herein;

(c) In failing to monitor, correct, supervise, regulate or otherwise determine the basis of the inconsistency of the manufacturer's testing and results of said testing in comparison with Defendants test results performed simultaneously on the same vaccine lots, all of which resulted in minor Plaintiff sustaining paralytic poliomyelitis as a result of said negligence;

(d) In otherwise being negligent as described in paragraph 17 above, as though said allegations were repeated herein in their entirety;

(e) In otherwise being negligent under the circumstances.

20. Defendant, by its agents, servants and employees, including, but not limited to the Food and Drug Administration and the Bureau of Biologics, was negligent in some or all of the following particulars:

(a) In failing to withdraw from the market the SOPV, specifically, the said vaccine manufactured by Lederle Laboratories, when Defendant knew, or should have shown, that the said vaccine failed to meet each and every one of the requirements and regulations necessary to insure the safety, purity and potency of the said vaccine;

(b) In failing to adequately enforce compliance on the part of Lederle Laboratories with the regulations pertaining to the giving of adequate warnings and precautions for the administration of the SOPV as were necessary;

(c) In failing to require Lederle Laboratories to provide adequate and accurate warnings, both as to statistical risk of disease, and also, as to the fact of non-compliance of various lots of vaccine with the regulations enacted to assure the safety, purity and potency of said vaccine;

(d) In otherwise being neligent under the circumstances.

21. As a result of the negligence of Defendant and its agents, servants and employees, minor Plaintiff suffered the severe and permanent paralysis of bulbar poliomeylitis, affecting, among other parts of his body, his four extremities and the muscles and other structures of his chest. He suffered severe respiratory distress, atelectasis of the lungs and associated hypoxemia. He suffered a severe scoliosis of the spine with the curvature being as great as 90 degrees. He suffered severe emotional and nervous shock and distress. All of the foregoing injuries are permanent in nature.

22. As a result of the bulbar poliomyetlitis, minor Plaintiff was confined to the Mercy Hospital of Pittsburgh from the time he was 2½ months of age on June 4, 1979 until April 18, 1980, when he was over a year old. Because of his paralysis which prevented him from breathing, a tracheostomy was performed, placing a permanent hole in his trachea, through which minor Plaintiff was maintained on a respirator. Minor Plaintiff continues to require ventilatory assistance periodically during the day as of the date of this Complaint. Following his discharge from Mercy Hospital, minor Plaintiff was additionally confined for rehabilitative care at the Rehabilitation Institute of Pittsburgh and, since that time, has been cared for on a full-time basis with 24 hour monitoring by his mother, father and sister. Minor Plaintiff has been forced to undergo surgery on various occasions in an attempt to reduce the scoliosis of his spine by the insertion of Harrington rods. Minor Plaintiff has been deprived of the use of his legs, his arms and his hands and must either be carried or conveyed from place to place with the use of a wheel chair; minor Plaintiff will be confined to same for the rest of his life. Minor Plaintiff has required respiratory care and management on a daily basis and will require same for the rest of his life. Minor Plaintiff has suffered from atrophy and contracture of all four of his limbs, as well as the musculature of other portions of his body, and will suffer same for the rest of his life.

23. As a further result of his injuries, in addition to the medical, surgical, medicinal, and rehabilitative care which minor Plaintiff has endured in the past, and in addition to the hospitalizations in the past, minor Plaintiff will be forced to submit to additional care and hospitalizations for the rest of his life.

24. As a further result of his injuries, minor Plaintiff has been forced to endure great pain, suffering, emotional distress and inconvenience and will endure same for the rest of his life. He suffers permanent disfigurement. He suffers from the embarrassment and humiliation resulting from same and will be forced to endure additional embarrassment and humiliation for the rest of his life.

25. As a further result of minor Plaintiff's injuries, he has been forced to be confined to his home at those times when he has not been confined in hospitals and other specialized rehabilitative facilities, and he will be forced to be confined to said home or facilities for the rest of his life.

26. As a further result of his injuries, minor Plaintiff's education and schooling and his opportunity to form normal and enriching social relationships has been retarded and will be retarded in the future. Both his earning capacity and his ability to participate in and enjoy the normal pleasures of life have been severely and permanently impaired.

27. As a further result of minor Plaintiff's injuries, he will be forced to expend large sums of money for doctors, hospitals and other items necessary for his care and treatment after he attains his majority.

Second Count

Arthur Berkovitz and Donna Berkovitz, his wife, in their own rights, Plaintiffs vs. United States of America, Defendant.

28. Plaintiffs incorporate by reference and make a part of this Count, all of the paragraphs of the First Count of this Complaint.

29. As a result of the injuries suffered by their son, the minor Plaintiff herein, Plaintiffs have been forced to expend large sums of money for hospitals, doctors, nurses and other items necessary for the proper care and treatment of their son, and they will be forced to expend

additional sums for like items in the future. To date, the medical care and treatment of minor Plaintiff has resulted in expenses of approximately $350,000.00.

30. As a further result of minor Plaintiff's injuries, Plaintiffs have suffered the loss of the services and companionship of their son and they will suffer similar loss in the future.

31. As a further result of minor Plaintiff's injuries, Plaintiffs have been forced to expend large portions of their time in the care and treatment of minor Plaintiff, and will be forced to do so in the future.

32. As a further result of the conduct of Defendant, Plaintiffs have suffered, and will suffer in the future, severe emotional loss and emotional distress and, in addition, have suffered, and will suffer in the future, the loss of the pleasures, joys and benefits of parenting a child who is able to enjoy the normal activities in which a healthy child participates.

33. As a further result of minor Plaintiff's injuries, Plaintiffs have been forced to expend, and will continue to expend, large portions of their time, physical, mental and emotional energy in the care and treatment of minor Plaintiff and they will be forced ot do so, and to continue to do so, in the future.

WHEREFORE, Plaintiffs claim damages against Defendant in sums in excess of $10,000.00.

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT
OF PENNSYLVANIA

Civil Action No. 84-2893

KEVAN BERKOVITZ, a minor, by his parents, and natural guardians, ARTHUR BERKOVITZ and DONNA BERKOVITZ, his wife; and ARTHUR BERKOVITZ and DONNA BERKOVITZ in their own rights,

Plaintiffs,

v.

UNITED STATES OF AMERICA,

Defendant.

DEFENDANT UNITED STATES OF AMERICA'S MOTION TO DISMISS

Defendant, United States of America, hereby moves this Court to dismiss the United States from the above-captioned action based on Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure on the grounds that the Court lacks jurisdiction over the subject matter of the act and the complaint fails to state a claim upon which relief can be granted. In support of this motion, the Court is respectfully referred to the attached Memorandum of Points and Authorities.

A proposed form of Order is attached for the Court's convenience.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 86-3444

KEVAN BERKOVITZ, a minor by his parents and natural guardians, ARTHUR BERKOVITZ, his wife, DONNA BERKOVITZ, and ARTHUR BERKOVITZ and DONNA BERKOVITZ, in their own right

vs.

UNITED STATES OF AMERICA,
Appellant

(D.C. Civ. No. 84-2893)

On Appeal from the United States District Court
for the
Western District of Pennsylvania—Pittsburgh

Present: HIGGINBOTHAM and SLOVITER, *Circuit Judges* and ROTH, *District Judge**

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the Western District of Pennsylvania—Pittsburgh and was argued by counsel February 19, 1987.

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* Honorable Jane R. Roth, United States District Court for the District of Delaware, sitting by designation.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the said District Court entered April 30, 1986, as certified to this Court pursuant to 28 U.S.C. § 1292(b) by order entered June 19, 1986, be, and the same is hereby reversed and the cause remanded to the said District Court with direction to grant the government's summary judgment motion. Costs taxed against the appellee.

ATTEST:

/s/ Sally Mrvos
Clerk

June 30, 1987

FILED
FEB 25 1988

No. 87-498

IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR PETITIONERS

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QUESTIONS PRESENTED

I. Whether employees of the regulating agency under section 262(d) of the Public Health Service Act have discretionary authority to license a live-virus vaccine that does not comply with the agency's safety regulations.

II. Whether the United States is immune from tort liability under section 2680(a) of the Federal Tort Claims Act when its employees act in violation of statutory and regulatory directives that do not provide for the exercise of policy judgment.

LIST OF PARTIES

The petitioners are Kevan Berkovitz, a minor, by his parents and natural guardians Arthur Berkovitz, his wife, Donna Berkovitz, and Arthur Berkovitz and Donna Berkovitz, in their own right.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
OPINIONS BELOW	1
JURISDICTION	1
STATEMENT OF THE CASE	2
SUMMARY OF ARGUMENT	8
ARGUMENT	10
I. Section 2680(a) Of The Federal Tort Claims Act Does Not Preserve Immunity For Negligent Conduct By Government Employees Which Violates Non-Discretionary Statutory And Regulatory Directives	10
II. Both The Statute And Regulations Here Impose Non-Discretionary Conditions Precedent To The Exercise Of Licensing Authority Regarding Live-Virus Vaccines. Agency Employees Who Issued Product Licenses In Violation Of Those Conditions Were Not Performing An Immunized Discretionary Function	14
A. Failure To Revoke The License Of Production Seed 45-B-85 After A Demonstrated Change In Neurovirulence Is Actionable Conduct	19
B. Issuance Of A Lot Release Approval For A Vaccine Lot Which Was Known To Be Excessively Neurovirulent Is Actionable Conduct	20
C. The Panel Majority Below Misconstrued The Scope Of Section 2680(a)	22

TABLE OF CONTENTS—Continued

	Page
III. *Varig Airlines* Protected The Policy-Making Function Of The FAA And The Implementation Of Policy In Accordance With Agency Directives. *Varig* Does Not Hold That Conduct Which Violates Non-Discretionary Directives Of Congress And Duly Promulgated Regulations Is Likewise Protected	24
IV. Section 2680(a) Does Not Provide *Per Se* Immunity For Regulatory Conduct	28
V. The Policies Underlying Both The Federal Tort Claims Act And The Public Health Service Act Support A Finding Of Liability	30
CONCLUSION	32
APPENDIX	1a

TABLE OF AUTHORITIES

CASES:	Page
Alabama Electric Cooperative, Inc. v. United States, 769 F.2d 1523 (11th Cir. 1985)	17
American School of Magnetic Healing v. Annulty, 187 U.S. 94 (1902)	14
Andrews v. Benson, 809 F.2d 1537 (11th Cir. 1987)	14
Aslakson v. United States, 790 F.2d 688 (8th Cir. 1986)	14
Baker v. United States, 817 F.2d 560 (9th Cir. 1987), *petition for cert. filed*, 56 U.S.L.W. 3539 (U.S. Jan. 13, 1988) (No. 87-1180)	17, 22, 28
Barton v. United States, 609 F.2d 977 (10th Cir. 1979)	17
Birnbaum v. United States, 588 F.2d 319 (2d Cir. 1978)	14
Block v. Neal, 460 U.S. 289 (1983)	11, 23
Brooks v. United States, 337 U.S. 49 (1949)	11
C.P. Chemical Co. v. United States, 810 F.2d 34 (2d Cir. 1987)	13
Chotin v. United States, 819 F.2d 1342 (6th Cir. 1987) (en banc)	25
Collins v. United States, 783 F.2d 1225 (5th Cir. 1986)	13, 28
Conley v. Gibson, 355 U.S. 41 (1957)	3
Dalehite v. United States, 346 U.S. 15 (1953)	*passim*
Drake Towing Company v. Meisner Marine Construction Company, 765 F.2d 1060 (11th Cir. 1985)	25
Eastern Airlines v. Union Trust Co., 221 F.2d 62 (D.C. Cir.), *aff'd sub nom., United States v. Union Trust Co.*, 350 U.S. 907 (1955)	23
Gray v. Bell, 712 F.2d 490 (D.C. Cir. 1983)	23
Griffin v. United States, 500 F.2d 1059 (3d Cir. 1974)	18, 21, 28
Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), *aff'd*, 500 F.2d 1059 (1974)	17, 21
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Heckler v. Chaney, —— U.S. ——, 105 S.Ct. 1649 (1985)	14

TABLE OF AUTHORITIES—Continued

	Page
Indian Towing Co. v. United States, 350 U.S. 61 (1955)	11, 23, 29, 31
Jayvee Brand, Inc. v. United States, 721 F.2d 385 (D.C. Cir. 1983)	14
Johnson v. District of Columbia, 118 U.S. 19 (1886)	12, 17
Kendall v. United States, 12 Peters 524 (1838)	14
Loge v. United States, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982)	18, 21
Marbury v. Madison, 1 Cranch 137 (1803)	12
Owen v. City of Independence, 445 U.S. 622 (1980)	10
Rayonier v. United States, 352 U.S. 315 (1957)	11, 23, 29, 30
Red Lake Band of Chippewa Indians v. United States, 800 F.2d 1187 (D.C. Cir. 1986)	13
Roberts v. United States, 176 U.S. 221 (1899)	17
Schindler v. United States, 661 F.2d 552 (6th Cir. 1891)	19
Spalding v. Vilas, 161 U.S. 483 (1896)	14
United States v. Aetna Casualty & Surety Co., 338 U.S. 366 (1949)	11
United States Fidelity & Guaranty Company v. United States, No. 87-5073, slip op. (3d Cir. Jan. 15, 1988)	13, 25, 28
United States v. Muniz, 374 U.S. 150 (1963)	11, 29
United States v. S.A. Empresa Aerea De Viacao Rio Grandense (Varig Airlines), 467 U.S. 797 (1984)	*passim*
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Westfall v. Erwin, —— U.S. ——, 56 U.S.L.W. 4087 (1988)	17

STATUTES AND REGULATIONS:

28 U.S.C. § 1254(1)	1
28 U.S.C. § 1346(b)	2, 10
28 U.S.C. § 2674	2, 10
28 U.S.C. § 2680(a)	*passim*

TABLE OF AUTHORITIES—Continued

	Page
42 U.S.C. § 201, *et seq.*	3
42 U.S.C. § 247b(j)(1)	27
42 U.S.C. § 262(a)	3
42 U.S.C. § 262(d)	3, 20
42 U.S.C. § 300aa-1, *et seq.*	31
42 U.S.C. § 300aa-15(b)	31
49 U.S.C. § 1421(a)(3)(C)	24
49 U.S.C. § 1421(c)	25
21 C.F.R. § 610.1	6, 20
21 C.F.R. § 610.2	21
21 C.F.R. § 610.2(a)	7
21 C.F.R. § 630.16	20
21 C.F.R. § 630.17(b)	7
21 C.F.R. § 630.17(e)	6, 21
42 C.F.R. § 73.3	4
42 C.F.R. § 73.5(a)	4, 16
42 C.F.R. § 73.9	6, 20
42 C.F.R. § 73.15(a)	20
42 C.F.R. § 73.110(b)(2)	4
42 C.F.R. § 73.110(b)(4)	5
42 C.F.R. § 73.110(b)(5)	6, 20
42 C.F.R. § 73.114(a)(3)	16
42 C.F.R. § 73.114(b)(1)(iii)	5, 16
42 C.F.R. § 73.116(g)	6

PUBLICATIONS:

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1987

No. 87-498

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF FOR PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. pp. 1a-27a) is reported at 822 F.2d 1322. The opinion of the district court (Pet. App. 28a-40a) has not been reported.

JURISDICTION

The judgment of the court of appeals was entered on June 30, 1987. Berkovitz' petition for rehearing or rehearing en banc was denied on July 22, 1987, with three judges indicating they would grant rehearing en banc. The petition for writ of certiorari was filed on September 25, 1987, and was granted on January 11, 1988. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATEMENT OF THE CASE

This case presents the question whether the United States is immune from tort liability under section 2680(a) of the Federal Tort Claims Act when its employees act in violation of statutory and regulatory directives that do not provide for the exercise of policy judgment.

The following points are not at issue here. First, there is no issue as to whether Petitioners have made out a *prima facie* case under sections 1346(b) and 2674 of the FTCA, providing that the government shall be liable in tort in the same manner and extent as a private individual, as determined by the law of the place where the act or omission occurred.[1]

Second, the validity of the agency's regulations is not questioned by Petitioners in this action. To the contrary, the only challenge to the authority of these regulations came from the agency employees who disregarded them, and from the agency representatives who now claim discretion to violate them.

Finally, there is no issue presented regarding the adequacy of proof to sustain the allegations. It is admitted for present purposes that the conduct in question violated agency regulations.[2]

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[1] Whether Petitioners' claim was actionable under state law was raised in the government's brief to the district court. Petitioners were granted leave to amend the complaint to aver specifically that the government's conduct increased the risk of harm to Kevan Berkovitz. The complaint, so amended, was found to state a cause of action under Pennsylvania law. The government did not include this issue in its request for certification for interlocutory appeal, and it was not considered or ruled on by the court of appeals.

[2] Since the issue was joined in the context of a Rule 12(b) motion to dismiss, the allegations of Petitioners' complaint must be accepted as true. The action may be dismissed only if it appears beyond doubt that Petitioners can prove no set of facts in support of the claim which would entitle them to relief. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957).

The facts of the case are as follows. On May 10, 1979, Kevan Berkovitz received a dose of live poliovirus vaccine from his pediatrician in Charleroi, Pennsylvania. One month later he contracted paralytic poliomyelitis. He was not yet three months old. The Communicable Disease Center determined that Kevan's polio was caused by the vaccine. (J.A. 9, ¶ 5)

In 1944 Congress passed the Public Health Service Act, 42 U.S.C. § 201, *et seq.* directing that biologic products, including live poliovirus vaccines, could not be produced or distributed by private manufacturers without a federal license. 42 U.S.C. § 262(a). The enabling provisions for federal regulation of biologic products are contained in Subchapter II, "General Powers and Duties". In section 262(d) Congress granted authority to the Department of Health and Human Services, through its Division of Biologic Standards (DBS), to issue a license:

> . . . only upon a showing that the establishment and products for which a license is desired meet standards, designed to insure the continued safety, purity and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. Licenses shall be issued, suspended, and revoked as prescribed by regulations.

42 U.S.C. § 262(d) (S.A. 3).[3] Regulations promulgated by the Surgeon General to implement the statute reiterated that, "A product license shall be issued only upon examination of the product and upon a determination

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[3] Section 262(d) was unaffected by the 1986 amendments to the Act, Pub. L. No. 99-660, § 105(a), § 315, 100 Stat. 3751, 3783 (1986).

that the product complies with the standards prescribed in the regulations." [4]

In the early 1960's DBS received a license application for an attenuated live poliovirus strain. This virus strain was the genetic parent of the vaccine which paralyzed Kevan. Regulatory criteria for original virus strains require the application to demonstrate that the virus was tested on a specified human population without harmful effect.[5] Further, it must be demonstrated that the virus was subjected to replication in the manner prescribed in the regulations—the manufacturing process being essentially a process of limited and controlled replication—and produced a consumer level vaccine that met all safety requirements.[6]

The application submitted to DBS demonstrated that the virus strain for which a license was sought *caused* paralysis in the human test population and was not, therefore, "without harmful effect." (J.A. 11, ¶ 17(c)). The data further demonstrated that the consumer level vaccine produced from the strain failed to meet the neurovirulence criteria of the regulations.[7] (J.A. 12, ¶ 17(g)).

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[4] 42 C.F.R. § 73.5(a) (S.A. 4). Under 42 C.F.R. § 73.3 (S.A. 4), the licensing application "shall not be considered as filed" if all required test data is not submitted.

[5] 42 C.F.R. § 73.110(b)(2) (S.A. 6).

[6] *Id.* It should be noted that there are three types of poliovirus, referred to as Types 1, 2 and 3. An original virus strain is separately licensed for each type. A type 1 strain is used to produce Type 1 seed viruses, which produce Type 1 monovalent vaccine pools (monopools). At the end of the manufacturing process, monopools of each of the three types are combined to form a trivalent vaccine. At issue here is the Type 3 strain, and a production seed and monopool derived therefrom.

[7] Neurovirulence is the capacity of an infectious agent to produce pathologic effects on the central nervous system. *Dorland's Medical Dictionary*, 26th Ed., 1985, p. 891. In this context it refers to the vaccine's ability to cause paralytic poliomyelitis. The neurovirulence

Although the strain violated the conditions for licensing prescribed in the regulations, an employee of the agency issued a product license permitting the virus to be used in vaccine manufacture.

After this license was issued, DBS received a product license application for a Type 3 [8] production seed virus grown from the original strain and designated "45-B-85". Seed viruses are the intermediate step in the manufacturing process—the first progeny of the original virus and the progenitor of vaccine monopools. Each production seed must be individually licensed; regulations require the application to demonstrate that the seed virus was tested for neurovirulence by intrathalamic, intraspinal and intramuscular injection in Macaca monkeys.[9] Neurovirulence is determined according to prescribed criteria, including: the number of monkeys showing lesions; the severity of the lesion; the dissemination of the lesion (distance from the inoculation site); and the rate of occurrence of paralysis.[10] The criteria are met:

> only if at least 80 percent of the animals survive the observation period and if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the reference.[11]

The data submitted with the application for 45-B-85 did *not* demonstrate that the seed had been subjected to the neurovirulence testing required by the regulations. In fact, the tests were not performed. The agency employee

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criteria, discussed *infra* in greater detail, are the most critical in evaluating vaccine safety.

[8] *See* n.6, *supra*.

[9] 42 C.F.R. § 73.110(b)(4) (S.A. 6).

[10] 42 C.F.R. § 73.114(b)(1)(iii) (S.A. 8).

[11] *Id.*

who reviewed the application nevertheless issued a product license for 45-B-85. (J.A. 12).

The production seed is used to manufacture vaccine monopools, which are combined to form the consumer level product. Data submitted to the agency [12] demonstrated that 45-B-85, after licensing, was producing vaccine monopools which exceeded the neurovirulence criteria of the regulations, indicating a deterioration of the seed's neurovirulence properties and genetic instability. (J.A. 12). The regulations provide that whenever there is evidence of a change in the neurovirulence of a production virus, it must be requalified in accordance with the original licensing criteria.[13] The regulations further provide that the Surgeon General shall recommend that a product license be suspended or revoked when the product fails to conform to regulatory standards.[14] The license may subsequently be reinstated only upon a showing of compliance with the original licensing criteria. Although 45-B-85 demonstrated non-compliance, no action was taken to revoke its license. (J.A. 12). It continued in use and subsequently produced the Type 3 monopool which caused Kevan's paralysis.

The vaccine monopools produced from the seed virus do not require product licenses. However, prior to distribution of a vaccine lot the manufacturer must test the vaccine for neurovirulence according to the prescribed criteria.[15] The regulations provide that no lot of vaccine

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[12] Under 42 C.F.R. § 73.116(g), the manufacturer must submit such test data to the agency.

[13] 42 C.F.R. § 73.110(b)(5) (S.A. 7).

[14] 42 C.F.R. § 73.9 (S.A. 5).

[15] 21 C.F.R. § 610.1 (S.A. 10); 21 C.F.R. § 630.17(e). The regulations were transferred from Title 42 to Title 21 when the regulatory responsibilities previously assigned to DBS were taken over by the Bureau of Biologics. This transfer occurred after the product licenses were issued, but before the vaccine lot was released.

[Continued]

shall be released unless it is demonstrated to meet regulatory neurovirulence standards.[16] The agency is empowered to require samples from the manufacturer and to conduct its own evaluation of neurovirulence prior to the vaccine's distribution. When the agency takes action under this section, the vaccine cannot be released unless the agency issues a lot release approval.[17] The data submitted by the manufacturer on the vaccine lot containing Kevan's dose demonstrated excessive neurovirulence. The agency conducted its own review and confirmed that the vaccine exceeded the regulatory standards. Knowing that the vaccine was excessively neurovirulent, an agency employee nonetheless issued a lot release approval permitting the vaccine to be distributed to members of the public, among them Kevan Berkovitz. (J.A. 13).

The vaccine paralyzed Kevan in all of his limbs and caused a scoliosis, or curvature, of his spine. He is able to breathe only with the assistance of a respirator. His injuries are permanent.

In response to Petitioner's complaint setting forth these allegations, the United States filed a motion to dismiss, alleging that the challenged conduct was a discretionary function. The district court denied the government's motion, holding that violation of non-discriminatory regulations by agency employees is not protected conduct under section 2680(a) of the Federal Tort Claims Act.[18] A divided panel of the court of appeals

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[15] [Continued]

References regarding the lot release approval will therefore be to Title 21, C.F.R.

[16] 21 C.F.R. § 630.17(b).

[17] 21 C.F.R. § 610.2(a) (S.A. 10).

[18] The district court granted the motion to dismiss with respect to the claims at ¶ 20 of Petitioners' complaint (J.A. 14), alleging that the government was negligent in failing to order withdrawal of defective vaccine lots after release and in failing to require the

reversed. The majority held that implementation of the statute and regulations by agency employees was an immunized "discretionary function" under section 2680(a), because neither the statute nor the regulations were found to impose any affirmative mandatory obligations on the agency. Judge Higginbotham dissented. He found that the statute created a duty to receive the showing of regulatory compliance and, further, created a duty not to license when the manufacturer "has shown the government that its vaccine is defective". (Pet. App. 25a). Agency employees who issued the contested licenses and lot release approval here were acting in violation of "the clear command of federal law". (Pet. App. 24a) Immunity for such conduct is not preserved under section 2680(a).

SUMMARY OF ARGUMENT

Section 2680(a) of the Federal Tort Claims Act preserves immunity for the policy and decisionmaking functions of the Executive. This section does not immunize conduct undertaken in execution of a statute, regulation or administrative plan unless: (i) it is performed with due care, or in accordance with official directives; or (ii) the conduct comprises a discretionary function, involving the authorized exercise of policy judgment. *Dalehite v. United States*, 346 U.S. 15 (1953); *Varig Airlines*, 467 U.S. 797 (1984). The conduct here was admittedly negligent and in violation of regulations which do not authorize the exercise of policy judgment. Immunity is not preserved for such conduct under section 2680(a).

Neither the enabling statute nor the regulations in this case confer discretion on agency employees regarding implementation of the licensing plan. The statute authorizes the regulating agency to issue licenses *only* upon

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manufacturer to provide more specific warnings to health care providers. Petitioners did not seek review of the dismissal of these claims, and they are not part of the case presented here. The government's motion was denied with respect to all remaining claims.

a showing that the vaccine *meets* regulatory standards. If Congress' condition precedent—demonstrated compliance with all applicable regulations—is not met, the agency has no authority to issue the license. Conduct of agency employees which goes beyond the scope of the agency's statutory authority cannot be immunized as discretionary function. *Hatahley v. United States*, 351 U.S. 173 (1956).

The regulations here are similarly non-discretionary. The precise scope of compliance review is defined in objective terms; the standards to be met are objective standards; and the regulations mandate that all regulatory criteria be complied with before the license may issue. There is no room in these regulations for an agency employee's subjective judgment of the best—or more expedient—course. Violation of non-discretionary agency regulations is not a protected function under section 2680(a).

A finding of liability in this case would be fully consistent with the policy and broad remedial objectives of the Federal Tort Claims Act. It cannot intrude on the prerogatives of the policy-maker to insist that his directives be obeyed by subordinates. Therefore, no policy justification exists for excepting this child from the Act's basic objective of providing compensation for those who are injured by the negligence of government employees.

The policy underlying the Public Health Service Act must also be considered. Congress acted wisely in imposing such stringent regulation of live-virus products, which if defective, present a risk of epidemic harm to the public health. The government employees who administer the statute and its following regulations must be made to conform to the judgment of the policy-makers regarding the non-discretionary criteria which qualify such products for licensing. The decision below set agency employees free to decide for themselves what live-virus products may be distributed to the public. That was *not* Congress' intent. The decision below should be reversed.

ARGUMENT

I. Section 2680(a) Of The Federal Tort Claims Act Does Not Preserve Immunity For Negligent Conduct By Government Employees Which Violates Non-Discretionary Statutory And Regulatory Directives.

The defense of sovereign immunity asserted by the United States has its origin in the royal prerogative claimed by medieval English monarchs.[19] The doctrine was grafted onto the common law of the United States and operated to insulate the government from liability for any claim of damage caused by the conduct of its agents and employees. Recognizing the anomaly presented by a broad assertion of royal prerogative in a constitutional democracy,[20] and seeking to correct the injustice and hardship which result when government is not held accountable for injuries inflicted by its employees, Congress passed the Federal Tort Claims Act in 1946. The Act provides that the federal government shall be liable in tort "in the same manner and to the same extent as a private individual under like circumstances." 28 U.S.C. § 2674 (S.A. 1).[21] Congress intended this language to embody a sweeping waiver of immunity, *United States v. Yellow Cab Co.*, 340 U.S. 543, 547 (1951), in order to achieve the just purpose of compensating vic-

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[19] Blackstone defined royal prerogative as:

> that special preeminence which the King hath over and above all persons, and out of the course of the common law, in right of his royal dignity . . . [The King] owes no kind of subjection to any other potentate on earth.

I Commentaries 239, 241-242.

[20] *See, Owen v. City of Independence*, 445 U.S. 622, 645, n.28 (1980) ("it has never been understood how the doctrine of sovereign immunity came to be adopted in the American democracy").

[21] Liability is to be determined "in accordance with the law of the place where the act or omission occurred." 28 U.S.C. § 1346(b) (S.A. 1).

tims of governmental misfeasance. *Indian Towing Co. v. United States*, 350 U.S. 61, 68-69 (1955). This Court has repeatedly held that the Act must be read broadly in conformity with its remedial objectives. *Brooks v. United States*, 337 U.S. 49, 51 (1949); *Block v. Neal*, 460 U.S. 289, 298 (1983); *United States v. Muniz*, 374 U.S. 150, 165-166 (1963); *Rayonier v. United States*, 352 U.S. 315, 320 (1957); and *United States v. Aetna Casualty & Surety Co.*, 338 U.S. 366, 383 (1949).

Exceptions to the Act's broad waiver of immunity—set forth in 28 U.S.C. section 2680—must be construed narrowly to cover "only those circumstances which are within the words and reason" of the statutory language. *Dalehite v. United States*, 346 U.S. 15, 31 (1953). The Court is not free to enlarge the exceptions, *United States v. Yellow Cab*, 340 U.S. 543, 548 (1951), or to create exceptions beyond those expressly provided by Congress. *Rayonier v. United States*, 352 U.S. 315, 320 (1957).

At issue in the present case is the scope of the exception set forth in section 2680(a), which preserves immunity for:

> (a) Any claim based upon an act or omission of an employee of the Government *exercising due care, in the execution of a statute or regulation*, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a *discretionary function* or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

(Emphasis added.) Thus, under section 2680(a), acts of a government employee performed in execution of a statute or regulation are protected if, and only if, the employee exercised due care. Because the conduct of government employees in this case admittedly was not undertaken with the requisite "due care", the challenged

conduct is immune only if that conduct is a "discretionary function" within the meaning of section 2680(a).[22]

The legislative history of section 2680(a) demonstrates that the "discretionary function" exception is intended to preserve immunity for "the discretion of the executive or the administrator to act according to one's judgment of the best course", including "determinations made by administrators in establishing plans, specifications or schedules of operations." *Dalehite v. United States*, 346 U.S. 15, 34 (1953) (reviewing legislative history). As this Court made clear in *Dalehite*, "discretionary function" immunity primarily shields official policy making. *Id.* at 36 ("where there is room for policy judgment and decision there is discretion"). This immunity has limited application to governmental conduct that merely implements policy choices. Implementing conduct is protected only if a government employee (i) acts to further a discretionary policy choice *in accordance with official directions*, *id.* at 36; or (ii) is empowered to exercise discretion in the implementation of a policy choice. *Id.* at 33.[23]

Acts by government employees that violate mandatory statutory or regulatory directives are not immune from liability under the Act. *Hatahley v. United States*, 351 U.S. 173 (1956). At issue in *Hatahley* were actions of employees of the Department of the Interior impounding

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[22] A prior legislative proposal, S. 2221, 77th Cong., 2d Sess. (1942), set out the two clauses of section 2680(a) in two subsections. The final legislation incorporated them into the same paragraph, indicating a legislative intent that they be read together.

[23] The legislative history indicates Congress' intent to incorporate the principles of pre-existing common law in section 2680(a). *Dalehite*, *supra*, 346 U.S. at 27. *Dalehite*'s analysis is consistent with common law. *See, e.g., Marbury v. Madison*, 1 Cranch 137, 170 (1803), (separate "political" powers of the Executive protected); *Johnson v. District of Columbia*, 118 U.S. 19, 21 (1886) (conduct requiring implementation "according to the general plan so adopted" was not within the ambit of protected discretion, that only exercise of judgment being that needed to determine that the requisites of the plan had been met.).

115 allegedly "abandoned" horses found grazing on public land. The Federal Range Code, issued under the authority of the Taylor Grazing Act, authorized such impoundment only if government employees provided the owners with prior written notice and an order to remove the livestock from public lands. The Code also provided an express definition of "abandoned" livestock.

The Court held that the notice provisions of the Code were express conditions precedent to the exercise of power under the local impoundment law, and further, that the statutory definition of "abandoned" livestock had not been met. Because the terms and conditions of the Code were not complied with, the agents were found to have acted wrongfully and without statutory authority. The first clause of section 2680(a) offered no protection for such conduct, since the agents had not exercised due care in executing the statute and regulations. Under the second clause, the Court made clear that government employees who act in violation of the terms and conditions of the law, and therefore *beyond* the law, are not entitled to "discretionary function" immunity. *Id.* at 752.

The Federal Courts of Appeals have uniformly refused to find "discretionary function" immunity for conduct of government employees that violates mandatory statutory or regulatory directives. *See, e.g., United States Fidelity & Guaranty Company v. United States*, No. 87-5073, slip op. at 8 (3d Cir. Jan. 15 1988) ("conduct cannot be discretionary if it violates the Constitution, a statute, or an applicable regulation"); *Red Lake Band of Chippewa Indians v. United States*, 800 F.2d 1187, 1196 (D.C. Cir. 1986) ("government official has no discretion to violate the binding laws, regulations or policies that define the extent of his official powers"); *Collins v. United States*, 783 F.2d 1225, 1230 (5th Cir. 1986) (failure to follow a non-discretionary regulation "represented disobedience of official directions, simple and unadorned"); *C.P. Chemical Co. v. United States*, 810 F.2d 34, 39 (2d Cir. 1987) ("this is not a case where an agency ignored its own regulations or the clear mandate

of statutory procedure"); *Aslakson v. United States*, 790 F.2d 688, 693 (8th Cir. 1986) (failure to adhere to established agency policies not protected); *Birnbaum v. United States*, 588 F.2d 319, 329 (2d Cir. 1978) ("a discretionary function can only be one within the scope of authority . . . as delegated by statute or regulations"); *Andrews v. Benson*, 809 F.2d 1537, 1542 (11th Cir. 1987) (for purpose of determining official immunity, violation of safety regulations is not discretionary activity); *Jayvee Brand, Inc. v. United States*, 721 F.2d 385, 389 (D.C. Cir. 1983) ("It is clear that the exception does not apply when a government employee fails to follow obligatory procedures in applying a rule that is itself an exercise of discretion.").[24]

II. Both The Statute And Regulations Here Impose Non-Discretionary Conditions Precedent To The Exercise Of Licensing Authority Regarding Live-Virus Vaccines. Agency Employees Who Issued Product Licenses In Violation Of Those Conditions Were Not Performing An Immunized Discetionary Function.

The question whether a government employee is performing a "discretionary function" immunized by section 2680(a) requires a careful, two-step analysis.

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[24] The common law cases are in accord. *See, American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108 (1902) (conduct which is "unauthorized by the statute under which [a government employee] assumes to act" is not protected); *Spalding v. Vilas*, 161 U.S. 483, 498 (1896) (department head "keeping within his authority" is protected); *Kendall v. United States*, 12 Peters 524, 610, 626 (1838) (where Congress imposes duty on Executive, "the duty and responsibility grow out of and are subject to the control of the law").

See, also, Heckler v. Chaney, —— U.S. ——, 105 S.Ct. 1649, 1657 (1985), (in protecting discretionary activity from judicial review under the Administrative Procedure Act, "Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers"). *Also, see*, Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U. Chi. L. R. 1300 (Fall 1987).

First, it must be determined whether Congress conferred discretion upon the agency to make policy judgments regarding how best to effectuate the intent of Congress, as expressed in the underlying the grant of authority. This is entirely a question of congressional intent, which depends on the particular enabling statute and will vary depending on the terms of that statute. If a government official seeks to make a policy choice that is *not* authorized by the enabling statute, the policy choice cannot qualify as a "discretionary function".[25]

Second, even if the statutory grant of authority confers some discretion upon the agency to determine the appropriate means to effectuate congressional intent, it must be determined whether or not the agency has established implementing regulations that confer discretion upon agency employees in the execution of the agency's policy choices. Within the bounds of its statutory authority, an agency may promulgate regulations that confer, or withhold, the power to exercise discretion in executing the intent of Congress. If agency regulations impose mandatory directives upon agency employees, an employee's decision to act in violation of the mandatory directives cannot qualify as "discretionary function".

The decisions of employees of the Division of Biologic Standards to license non-complying live poliovirus products cannot come within the "discretionary function" exception. Congress gave DBS no discretionary authority to issue a license when compliance with applicable safety regulations was not demonstrated. The regulations promulgated by the agency gave agency employees no discretionary authority in determining whether compliance was demonstrated.

By statute, DBS was empowered by Congress to issue licenses permitting the private manufacture of biologic

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[25] *See, Hatahley v. United States*, 351 U.S. 173 (1956) and cases cited, *supra*, at 13 and n.21.

products *only* upon a *showing* that the product for which a license is sought *meets* regulatory standards designed to insure its safety. 42 U.S.C. § 262(d) (S.A. —). Demonstrated compliance with *all* regulatory standards is a non-discretionary condition precedent to the exercise of power under this statute. No exceptions are provided; the grant of power is thus strictly limited. The government employee who issued the product licenses for the original virus strain and for the production seed admittedly did not comply with the express condition of the statute. Such conduct, which exceeded the agency's statutory authority, is not an immunized "discretionary function" under section 2680(a).

The regulations promulgated by the agency gave agency employees no authority to exercise policy judgment in determining whether the conditions of licensing were met. In the section titled, "Product licenses; issuance and conditions," the regulations reiterate that a license shall be issued "*only* upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations."[26] Compliance with regulatory standards is determined by evaluation of precise and objective criteria. No policy judgment is needed, for example, to determine whether two paralyzed Macaca monkeys is a greater number than none; whether three lesions are more than two; whether a lesion which advanced 2 cm beyond the point of inoculation has a greater spread than one which advanced .5 cm from the inoculation site.[27] Nor is policy judgment needed to determine whether at least 16 of 20 suckling mice less than 24 hours old survived for 14 days after intracerebral injection of .01 ml and intraperitoneal injection of .10 ml of the monovalent pool.[28] There is no room here for

[26] 42 C.F.R. § 73.5(a) (S.A. 4).

[27] 42 C.F.R. § 73.114(b)(1)(iii) (S.A. 7).

[28] 42 C.F.R. § 73.114(a)(3).

discretion, for a licensing decision based on an administrator's subjective judgment of the best course.[29]

In promulgating the regulations, the Surgeon General expressly *rejected* proposals that the regulations provide for flexibility in determining regulatory compliance. For example, it was suggested that the neurovirulence criteria require that the lot not *significantly* exceed the reference; that is not exceed *the range established for* the reference; that it is acceptable if the lot is *in the same range* as the reference.[30] The last of these proposals was made by Dr. Albert Sabin, who produced the original attenuated strain. The Surgeon General rejected Dr. Sabin's proposal, along with the others.

Aside from the majority below, every federal court which has considered this statutory and regulatory scheme has found it to impose mandatory obligations on the regulating agency.

Baker v. United States, 817 F.2d 560 (9th Cir. 1987), *petition for cert. filed*, 56 U.S.L.W. 3539 (U.S. Jan. 13, 1988) (No. 87-1180) involved a claim that an original poliovirus strain had been licensed in violation of the statute. In *Baker* data demonstrating the successful performance of all required tests had not been submitted with the licensing application. The government claimed

[29] Even the panel majority below agreed that conduct which can be measured by a readily ascertainable standard is not discretionary activity. (Pet. App. 14a). *See, also, Alabama Electric Cooperative, Inc. v. United States*, 769 F.2d 1523 (11th Cir. 1985); *Barton v. United States*, 609 F.2d 977, 979 (10th Cir. 1979). Also, *see, Westfall v. Erwin*, —— U.S. ——, 56 U.S.L.W. 4087, 4089 (1988) (discretion is more than "a modicum of choice"). At common law, *see, Roberts v. United States*, 176 U.S. 221, 231 (1899) (that a public officer was required to construe a statute in order to ascertain his duty under it did not render the duty discretionary); *Johnson v. District of Columbia*, 118 U.S. 19, 21 (1986), *supra*, n.23.

[30] *Griffin v. United States*, 351 F. Supp. 10, 26 (E.D. Pa. 1972), *aff'd*, 500 F.2d 1059 (3d Cir. 1974).

that the licensing was a discretionary function under section 2680(a). The court of appeals reviewed the statute and the regulations, concluding that:

> In this case the Secretary may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted . . . Agency employees charged with enforcing poliovirus vaccine safety standards must require the submission of the test data. As to that there is no discretion.

Id. at 566.

In *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), plaintiffs contended that an original poliovirus strain had been licensed in violation of the statute and regulations. The court of appeals similarly rejected the government's claim that the conduct was protected discretionary function, holding that:

> The Secretary has no discretion to disregard the mandatory regulatory commands pertaining to criteria a vaccine must meet before licensing its manufacture or releasing a particular lot of vaccine for distribution to the public.

Id. at 1273.

In *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974)[31], which involved a lot release approval under the regulations, the court characterized the requirements of the regulations as "strict" and held that "no discretion was conferred to disregard the mandatory regulatory command." *Id.* at 1068. The court concluded that, "Although Congress has provided that activity within the authority of a Government official, if a 'discretionary function', may not be the basis of Government liability even if negligent or an abuse of discretion, Con-

[31] *Griffin* was overruled by the decision of the panel majority below. Prior to that decision, *Griffin* had been relied on or cited with approval in more than 80 cases covering every federal circuit in the country.

gress has not immunized such activity if it exceeds the authority conferred." *Id.* at 1069.[32]

The conclusion reached by these courts is the only logical construction of the statutory and regulatory language. Congress unquestionably has the power to impose mandatory executory obligations on an agency of its creation, thereby limiting the agency's power. The statute duly enacted by Congress clearly imposes such restrictions on agency authority here: *Licenses may be issued only upon a showing that the product meets regulatory standards designed to insure its safety.* The regulations promulgated to carry this statute into effect are equally restrictive. Neither confers discretionary authority to license a non-complying live-virus vaccine.

A. *Failure To Revoke The License Of Production Seed 45-B-85 After A Demonstrated Change In Neurovirulence Is Actionable Conduct.*

After production seed 45-B-85 was licensed, it demonstrated a change in neurovirulence, triggering the requirement that its license be revoked.[33] No action was taken, however, and the seed subsequently produced the vaccine monopool that paralyzed Kevan Berkovitz. Although what is at issue here is a failure to undertake

[32] *See, also, Schinder v. United States*, 661 F.2d 552 (6th Cir. 1981) reversing the lower court's dismissal of a vaccine licensing complaint. *Schindler*, however, did not pass on the mandatory or non-mandatory character of the regulations, remanding instead for development of a factual record. At trial the action was dismissed for failure of proof regarding regulatory non-compliance.

[33] The panel majority below did not distinguish among the four separate allegations of misconduct presented in the complaint. Each allegation rests on the same fundamental proposition: that there is no discretion to violate mandatory regulations. However, insofar as the revocation and lot release approval issues do not involve an explicit statutory directive, and depend on regulations distinct from those governing the licensing claims, the analysis is not identical.

affirmative conduct, the analysis is consistent with that in the preceding section.

The enabling statute makes explicit reference to regulation of the *continued* safety of the vaccine. 42 U.S.C. § 262(d). Given the ability of live viruses to change and return to morbid neurovirulence, the emphasis on continued safety is critical to the regulatory scheme. The regulations provide that whenever "the product for which the license has been issued, fails to conform to the standards in the regulations", the Surgeon General shall recommend revocation of the product license.[34] Once revoked, the license can only be reinstated upon a showing of compliance with regulatory standards.[35]

It is admitted that data submitted to the agency demonstrated that 45-B-85 had not been able to maintain the neurovirulence properties prescribed in the regulations and that failure to revoke its product license violated agency regulations. Such conduct is actionable under the construction and authorities set forth in the preceding Argument.[36]

B. *Issuance Of A Lot Release Approval For A Vaccine Lot Which Was Known To Be Excessively Neurovirulent Is Actionable Conduct.*

Consumer level vaccine lots do not require a product license. However, the manufacturer is required to test each vaccine lot for compliance with prescribed neurovirulence criteria[37] and to submit the test results to the

[34] 42 C.F.R. section 73.9 (S.A. 5).

[35] 42 C.F.R. section 73.15(a) (S.A. 5).

[36] It should be noted that Petitioners' Complaint does not refer to revocation of license, but rather to enforcement of the requalification requirement of § 73.110(b)(5) (S.A. 7). Particularly for the purposes of a motion to dismiss (*see*, n.2, *supra*), the complaint fairly encompasses the revocation issue.

[37] 21 C.F.R. §§ 610.1, 630.16 (S.A. 10). *See* n.15 *supra* regarding transfer of the regulations from Title 42, C.F.R., to Title 21, C.F.R.

agency,[38] which is empowered to intervene before the vaccine is distributed in order to confirm compliance with neurovirulence standards.[39] A strong argument can be made that the duty to confirm compliance is mandatory when the manufacturer's data demonstrates excessive neurovirulence, as it did here.[40] However, even if the *decision* to test were found to be discretionary, the implementing conduct is not. This section has been interpreted in *Griffin v. United States*, 500 F.2d 1059 (3d Cir. 1974) and *Loge v. United States*, 662 F.2d 1268 (8th Cir. 1981), *cert. denied*, 456 U.S. 944 (1982) as authorizing the issuance of the lot release approval only upon a showing of compliance with the neurovirulence criteria. Once the agency takes action under this section, its duties are the same as those which govern the issuance of product licenses: to review data and issue the lot release approval only upon a showing of regulatory compliance.[41]

It is admitted that the issuance of the lot release approval violated agency regulations. Under the preceding discussion, such conduct cannot be immunized as discretionary function.

[38] 21 C.F.R. § 630.17(e).

[39] 21 C.F.R. § 610.2 (S.A. 10).

[40] The regulations must be interpreted in light of the statutory directive that they be designed to insure the continued safety of the vaccine. It would be wholly inconsistent with the duties imposed on the agency by the overall statutory and regulatory scheme to contend that the agency was *not* required to act under this section when it had knowledge that a vaccine lot was dangerously neurovirulent. Further, Petitioners will prove at trial that the agency interpreted the regulation as mandatory when excessive neurovirulence was demonstrated.

[41] Testimony in *Griffin v. United States*, 351 F. Supp. 10 (1972), *aff'd*, 500 F.2d 1059 (1974), indicated that this was the agency's own interpretation of the regulation.

C. *The Panel Majority Below Misconstrued The Scope Of Section 2680(a).*

The agency employees whose conduct is in question here admittedly failed to use due care in executing the statute and regulations; were not empowered to make policy judgments; and were not acting in accordance with official directives. To the contrary, their conduct violated the directives of both Congress and the Surgeon General. Immunity is not preserved for such conduct under section 2680(a).

The majority below made three significant errors in analyzing this conduct. First was the contention that "Berkovitz can point to no regulation requiring the FDA to do anything. In other words, no regulation imposes a non-discretionary duty." (Pet.App. 17a-18a). This analysis misses the central contention of the lawsuit—that the agency *did* do something that it lacked the power to do. The duty *not* to act, where the conditions precedent to the lawful exercise of power are not met, is no less imperative than a requirement to undertake affirmative conduct.[42]

Second, the majority created an unprecedented category of protected conduct in holding that "non-discretionary operational level acts and omissions taken in furtherance of planning level discretionary decisions" are protected. (Pet.App. 16a). The majority's reliance on *Dalehite* for this proposition is wholly unfounded, since the majority omits *Dalehite*'s critical requirement that such conduct be *in accordance with official directions.*

[42] In Judge Higginbotham's analysis, the existence of the condition precedent to licensing creates an affirmative duty to receive the required showing of regulatory compliance. (Pet. App. 25i). This was also the approach of the court in *Baker v. United States*, 817 F.2d 560 (9th Cir. 1987), construing the same statute.

Following *Dalehite*, in *Indian Towing v. United States*, 350 U.S. 61 (1955), the Court held that although the Coast Guard's decision to undertake operation of a lighthouse was an act of discretion, the Coast Guard was nonetheless liable under the Act for negligent execution of that policy in failing to keep the light in working order.[43] *See also, Block v. Neal*, 460 U.S. 289, 293 (1983); *Rayonier, Inc. v. United States*, 352 U.S. 315 (1957); *Eastern Airlines v. Union Trust Co.*, 221 F.2d 62, 74 (D.C. Cir.), *aff'd sub nom., United States v. Union Trust Co.*, 350 U.S. 907 (1955).

Further, the legislative history indicates that the one example on which there was consensus regarding Congress' consent to suit is that of the much-maligned government truck driver. If a government truck carrying ammonium nitrate fertilizer to the dock for loading ran a red light and crashed, causing an explosion, the government would be liable. Although the driver was furthering a discretionary plan, his conduct is "sufficiently separable" from policy-making conduct to be actionable.[44] The majority's construct, which would protect all implementing conduct, is plainly at odds with the statutory language, the legislative history and all prior precedent.

Finally, the majority's erroneous result was based in large part on a misunderstanding of this Court's decision in *Varig Airlines*. Properly understood, *Varig* compels a finding that the conduct at issue in the present case is

[43] In *Indian Towing* the government conceded that the discretionary function exception did not apply to such implementing conduct and instead argued that operation of a lighthouse was a "governmental function" which was entitled to *per se* protection under the Act. The Court found this definition of protected conduct to be "so finespun and capricious as to be almost incapable of being held in the mind for adequate formulation" and refused to endorse it. *Id.* at 68.

[44] *Gray v. Bell*, 712 F.2d 490, 515 (D.C. Cir. 1983).

not within the immunity preserved for "discretionary function".

III. *Varig Airlines* Protected The Policy-Making Function Of The FAA And The Implementation Of Policy In Accordance With Agency Directives. *Varig* Does Not Hold That Conduct Which Violates Non-Discretionary Directives Of Congress And Duly Promulgated Regulations Is Likewise Protected.

In *United States v. S.A. Empresa Aerea De Viacao Rio Grandense*, 467 U.S. 797 (1984), hereafter *Varig Airlines*, the Court expressly reaffirmed the reasoning of *Dalehite*.

The decision-making process was itself directly challenged in *Varig* by the allegation that the FAA's choice of a spot-inspection plan was negligent. Since the FAA was given express discretionary power to decide how, whether and when to inspect,[45] immunity was necessary to protect the agency's decision-making prerogatives. Insofar as the challenged conduct of FAA inspectors was performed in accordance with the plan, it was also protected. *Id.* at 814. As the Court again noted, what is protected by section 2680(a) is "legislative and administrative decisions grounded in social, economic, and political policy." *Id.*

That is not the case presented here. The Surgeon General's *plan* is not being challenged, and the only conduct complained of is conduct which was distinctly *not* in accordance with his official directives. The integrity of the agency's decision-making process is in no way jeopardized by these allegations.

Further, in *Varig* the FAA's statutory power to certify aircraft was unrestricted. The Administrator was

[45] 49 U.S.C. § 1421(a)(3)(C) authorized the Administrator to prescribe reasonable regulations governing inspection of aircraft and "in the discretion of the Administrator, the period for, and the manner in which, such inspection . . . shall be made."

given express power to issue certificates *whether or not* the plane met regulatory standards.[46] The ultimate act complained of in *Varig*—issuance of a type certificate for a non-complying plane—was within the scope of the agency's statutory authority.

Agency power here was restricted by a mandatory condition precedent to the exercise of licensing power. DBS was empowered to issue a license for biologic products *only* upon a showing of regulatory compliance. No exemptions were authorized. The ultimate act complained of—issuance of a license for a virus strain and seed that did *not* comply with regulatory standards—was beyond the agency's statutory authority.

In addition, discretion was conferred by the *regulations* in *Varig*, which specifically empowered subordinate employees to make policy judgments in implementing the inspection plan. *Id.* at 820. Thus, the inspectors' conduct is protected, even if negligent.[47]

In the present case, the regulations did not give agency employees discretion to make policy judgments in deter-

[46] 49 U.S.C. § 1421(c) authorizes the Administrator to "grant exemption from the requirements of any rule or regulation . . . if [he] finds that such action would be in the public interest."

[47] Because *Varig* considered a failure to inspect, the question nominally left unanswered was whether an actual negligent inspection by the FAA would be protected. Since negligence is irrelevant where operational employees are authorized to exercise discretion, the conduct would be protected. It should be noted that although *Varig* did not directly address *Dalehite's* dichotomy between planning and implementing conduct, the Court's emphasis on "the nature of the conduct" as one of the principal determinants of discretionary function has been analogously read in the lower courts. *See, e.g., United States Fidelity & Guaranty Company v. United States*, No. 87-5073, slip op. at 10-11 (3d Cir. Jan. 15, 1988); *Chotin v. United States*, 819 F.2d 1342, 1347 (6th Cir. 1987) (en banc); *Drake Towing Company v. Meisner Marine Construction Company*, 765 F.2d 1060, 1065 (11th Cir. 1985).

mining regulatory compliance. The regulations defined precisely the scope of the compliance review and directed that review of the licensing application in accordance with the regulations be undertaken in *every* case.

The panel majority below disregarded these distinctions, relying instead on the broad statement that, "It would be incongruous to conclude that Congress intended the FAA to exercise a lesser supervision over the safety of aircraft than the FDA was to exercise over the safety of polio vaccine." (Pet. App. 20a)

There are two problems with this statement. First, it elevates the court's policy view on the advisability of congruity in federal regulation above the expressed judgment of Congress. The plain language of the empowering statutes demonstrates the differences in the two schemes Congress devised.

Addressing the statement on its merits, the decision to create a more stringent scheme regarding biologic products is not "incongruous." Relevant factors to be considered in devising a regulatory scheme would presumably include the feasibility of comprehensive government regulation, the magnitude of risk presented by unregulated private activity, and the public interest to be advanced by government involvement.

It would not be feasible for the FAA to meet a mandatory obligation to inspect every plane and confirm compliance with every regulation. A Boeing 707 cannot readily be delivered to an FAA lab for compliance review. Not only the size of the "product" to be regulated, but also the number of aircraft, the number of discrete component parts in each plane, the number of manufacturers and the volume of applicable regulations (covering over 500 pages in Title 14 of the Code), would make a mandatory system unworkable.[48] And so Congress charged the FAA only with the duty of "promoting" air safety by "monitoring" compliance, in whatever way the agency deemed appropriate.

It *is*, however, feasible for the agency regulating biologic products to meet mandatory obligations. There is no problem with size: all of the poliovirus vaccine produced since 1963 would fit into the overhead compartments of one Boeing 707. The regulations, which cover only 9 pages in the Code, are objective and precise; determining compliance requires only that an agency employee review the data delivered to his or her office and numerically match the test results against the Reference strain. If adequate data are not submitted, or if the data demonstrate excessive neurovirulence or other regulatory non-compliance, the only action required of the employee is to reject the application.

The comparative risk presented by the unregulated manufacture of live-virus products also justifies the more stringent regulatory scheme. The number of people put at risk by a defective plane is not insignificant. However, one vaccine monopool produces *one million* doses of live-virus vaccine, capable of producing contagious and morbid paralytic disease not only in recipients, but also in those with whom they come in contact.

Regarding public interest, there is an issue beyond the avoidance of risks to the public health. No one is *required* to board an airplane, nor does the federal government involve itself in persuading members of the public to travel by air. The federal government *does*, however, involve itself in promoting mass immunization programs.[49]

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[48] *See*, National Academy of Sciences, Committee on FAA Airworthiness Certification Procedures, *Improving Air Safety*, p. 29 (1980), discussing the volume of applications for type certificates.

[49] *See, e.g.*, 42 U.S.C. § 247b(j)(1); Staff of House Subcommittee on Health and The Environment, 99th Cong., 2d Sess., *Report on Childhood Immunizations* (Comm. Print 1986), pp. 50-55.

All fifty states and the District of Columbia *require* that children receive polio vaccine before they can be admitted to school.[50] The government makes affirmative efforts to persuade the public to participate in these programs, and the public responds, based in some measure on the assurance of involvement by a corporate body whose only concern, they believe, is not profit, but their collective well-being.

For all of these reasons, it was not "incongruous" for Congress to impose a non-discretionary condition precedent to licensing power, requiring this agency to be more than an occasional "monitor" of industry compliance.

Varig reviewed a statutory and regulatory plan shot through with discretion, and the implementing conduct demonstrated faithful execution of the plan. That is *not* the case presented here. *Varig* does not, therefore, support a finding of immunity.

IV. Section 2680(a) Does Not Provide *Per Se* Immunity For Regulatory Conduct.

Implicitly recognizing that the conduct at issue here does not involve discretionary function, the government argued to the court below that *all* regulatory conduct, including violation of mandatory regulations, enjoys *per se* immunity under section 2680(a). This proposition has been rejected by every federal court to which the government has presented it, including the panel majority below. (Pet. App. 12a-15a)[51] The reasons are sound.

First, there is nothing in the language of the statute which supports the argument. If Congress had intended

[50] *Id.* at Appendix B.

[51] *See, e.g., Collins v. United States*, 783 F.2d 1225, 1229 (5th Cir. 1986); *Baker v. United States*, 817 F.2d 560, 565 (9th Cir 1987); *United States Fidelity & Guaranty Company v. United States*, No. 87-5073, slip op. at 10 (3d Cir. Jan. 15, 1988); *Griffin v. United States*, 500 F.2d 1059, 1063-64 (3d Cir. 1974).

to protect all regulatory conduct, they could very easily have done so. A third clause could simply have been added to section 2680(a), providing that "all regulatory activities of federal agencies are exempt." However that was not done. The statute enacted by Congress provides that only *discretionary acts* of federal agencies, including regulatory agencies, are immune. The inapplicability of a *per se* approach to this section is indicated by the Court's observation that there are no bright line tests in this area, that the precise contours of the exception cannot be defined, and that analysis must proceed on a case by case basis. *Dalehite, supra*, 346 U.S. at 35; *Varig Airlines, supra*, 467 U.S. at 813. That a *per se* approach would contravene Congress' intent is further evidenced by the legislative history, indicating that "the common law torts of employees of regulatory agencies would be included within the scope of the bill to the same extent as torts of non-regulatory agencies."[52]

The government has previously urged the Court to adopt a *per se* approach extending immunity to all "governmental functions". The Court has repeatedly rejected such a construction as not within the express terms of the statute.[53]

In *Varig*, the Court chose not to accept the government's invitation to extend *per se* immunity to regulatory conduct, engaging instead in a careful analysis of the extent of the FAA's lawful discretionary power. Even the broadest language in *Varig*—"Whatever else the discretionary function exception may include, it plainly was intended to encompass the discretionary acts of the government acting in its role as a regulator of the

[52] *Dalehite, supra*, 346 U.S. at 29, n.21.

[53] *Indian Towing Co. v. United States*, 350 U.S. 61, 68 (1955); *Rayonier v. United States*, 352 U.S. 315, 319 (1957); *United States v. Muniz*, 374 U.S. 150 (1963).

conduct of private individuals"—acknowledges that only the *discretionary acts* of regulators are protected. *Varig Airlines, supra*, 467 U.S. at 813-814. Further, *Varig* stressed that what is important in the analysis of discretionary function is the nature of the conduct, not the status of the actor. *Varig Airlines, supra*, 467 U.S. at 813. The actor's status as regulator, therefore, should not be relevant.

The cases refusing to adopt a *per se* approach are fully consistent with the Court's acknowledgment that it is not free to enlarge the exceptions to liability under the Act [54] or to read into the Act exceptions not expressly provided by Congress.[55]

Petitioners respectfully submit that the Court should put to rest, with its opinion in this case, the government's assertion of *per se* immunity for regulatory conduct.

V. The Policies Underlying Both The Federal Tort Claims Act And The Public Health Service Act Support A Finding Of Liability.

The principal justification for the exception to liability in section 2680(a) is "to prevent judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic and political policy". *Varig Airlines, supra*, 467 U.S. at 814. An exception which prohibits *judicial* second-guessing of policy decisions cannot be read to protect agency subordinates engaged in that very conduct. The exception would swallow itself if extended to cover subordinate acts which flout the expressed policy of the Executive, thereby undermining the integrity of the decision-making process. Further, a holding that agency functionaries must adhere to the rules laid down by the policy-makers cannot be said to

[54] *United States v. Yellow Cab Co.*, 340 U.S. 543, 548 (1951).

[55] *Rayonier v. United States*, 352 U.S. 315, 320 (1957).

impair the agency's ability to function. To the contrary, on a policy level the position of the decision-maker is strengthened. On an operational level, holding employees engaged in non-discretionary conduct to a standard of due care can only improve the functioning of the agency.[56]

The avoidance of financial liability is an insufficient justification for extending immunity to the conduct here, particularly given the Act's fundamental objective to *provide* relief for people injured by negligent government employees. As this Court has held, it should not "as self-constituted guardian of the Treasury import immunity back into a statute designed to limit it." *Indian Towing Co. v. United States*, 350 U.S. 61, 69 (1955).

There is no policy justification for excepting Kevan Berkovitz from the Act's fundamental objective to provide compensation for those injured by the wrongdoing of government employees.[57]

The policy underlying the Public Health Service Act should also be considered. Congress purposefully imposed limitations on the agency's authority to license biologic products, including live-virus products capable of producing epidemic disease. The agency, acknowledging its obligation under the statute to promulgate regulations designed to insure the continued safety of such products, adopted stringent, non-discretionary licensing criteria.

[56] An extensive discussion of the policy justifications for section 2680(a), and their inapplicability to violation of mandatory regulations, is found in Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U. Chi. L. Rev. 1300, 1327-1334 (Fall 1987).

[57] In November, 1986, Congress passed legislation to provide compensation, without proof of negligence, for injuries caused by certain vaccines, including polio vaccine. 42 U.S.C. § 300aa-1, *et seq.* For injuries occurring before the effective date of the Act, as Kevan's, compensation is limited to unreimbursed medical expenses incurred subsequent to a determination of entitlement. 42 U.S.C. § 300aa-15(b).

Subordinate employees of the regulating agency cannot be permitted to disregard those criteria and decide for themselves what biologic products may be distributed to the public. The judgment of Congress, and of the Surgeon General, must be adhered to.

CONCLUSION

The judgment of the court of appeals, remanding to the district court with instructions to dismiss Petitioners' action, should be reversed.

Respectfully submitted,

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STATUTORY APPENDIX

STATUTORY APPENDIX

28 U.S.C. § 1346. United States as defendant

* * * *

(b) Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

* * * *

28 U.S.C. § 2674. Liability of United States

The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances, but shall not be liable for interest prior to judgment or for punitive damages.

If, however, in any case wherein death was caused, the law of the place where the act or omission complained of occurred provides, or has been construed to provide, for damages only punitive in nature, the United States shall be liable for actual or compensatory damages, measured by the pecuniary injuries resulting from such death to the persons respectively, for whose benefit the action was brought, in lieu thereof. June 25, 1948, c. 646, 62 Stat. 983.

28 U.S.C. § 2680. Exceptions

The provisions of this chapter and section 1346(b) of this title shall not apply to—

(a) Any claim based upon an act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation, whether or not such statute or regulation be valid, or based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.

42 U.S.C. § 262. Regulation of biological products

* * * *

(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

* * * *

Title 42, C.F.R. (1961)

LICENSES: PROCEDURE

§ 73.2. Two forms of licenses.

There shall be two forms of licenses: establishment and product.

§ 73.3 Application for establishment and product licenses; procedure for filing.

To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Division of Biologics Standards, on forms prescribed for such purpose, and in the case of an application for a product license, shall submit data derived from laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity and potency, a full description of manufacturing methods, data establishing stability of the product through the dating period, sample(s) representative of the product to be sold, bartered or exchanged or offered, sent, carried or brought for sale, barter or exchange, summaries of results of tests performed on the lot(s) represented by the submitted sample(s), and specimens of the labels, enclosures and containers proposed to be used for the product. An application for license shall not be considered as filed until all pertinent information and data shall have been received from the manufacturer by the Division of Biologics Standards.

• • • •

§ 73.5 Product licenses: issuance and conditions.

(a) *Examination—compliance with standards.* A product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations in this part: *Provided*, That no product license shall be issued except upon a determination that the establishment

complies with the establishment standards prescribed in the regulations contained in this part, applicable to the manufacture of such product.

• • • •

§ 73.9 Issuance, revocation or suspension.

• • • •

The Surgeon General shall recommend to the Secretary that a license be suspended or revoked whenever he finds, after notice and opportunity for hearing, that . . . (c) the establishment or any location thereof, or the product for which the license has been issued, fails to conform to the standards in the regulations in this part, as herein prescribed or as hereafter amended, designed to insure the continued safety, purity, and potency of the manufactured product.

• • • •

§ 73.15 Licenses: reissuance.

(a) *Compliance with standards.* An establishment or product license, previously suspended or revoked, whether upon application, or for failure to comply with standards or changes in standards prescribed in the regulations in this part, may be reissued or reinstated upon a showing of compliance with required standards and upon such inspection and examination as may be considered necessary by the Director of the Division of Biologics Standards.

• • • •

ADDITIONAL STANDARDS: POLIOVIRUS VACCINE, LIVE, ORAL

§ 73.110 The product.

(a) *Proper name and definition.* For the purpose of section 351(a)(2) of the Act and § 73.1(k), the proper name of this product shall be "Poliovirus Vaccine, Live, Oral", followed by a designation of the form in which the vaccine is distributed by the manufacturer. The vaccine shall be a preparation of one or more live, attenu-

ated poliovirus grown in monkey kidney cell cultures, prepared in a form suitable for oral administration.

(b) *Criteria for acceptable strains and acceptable seed virus.* (1) Strains of attenuated poliovirus Types 1, 2, and 3 used in the manufacture of the vaccine shall be identified by: (i) Historical records including origin and techniques of attenuation, (ii) antigenic properties, (iii) neurovirulence for monkeys, (iv) pathogenicity for other animals and tissue cultures of various cell types, and (v) established virus markers including rct/40, d, MS.

(2) Poliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless, (i) data are submitted to the Surgeon General which establish that each strain is free of harmful effect upon administration in the recommended dosage to at least 100,000 people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained, and, (ii) each such strain produces a vaccine meeting the safety and potency requirements of §§ 73.114(b), 73.115, and 73.117. Susceptibility shall be demonstrated by blood tests, stool examination and other appropriate methods.

(3) Each seed virus used in manufacture shall be demonstrated to be free of extraneous microbial agents.

(4) No seed virus shall be used for the manufacture of poliovirus vaccine unless its neurovirulence in Macaca monkeys is no greater than that of the NIH Reference Attenuated Poliovirus. The neurovirulence of the seed virus shall be demonstrated by the following tests to be performed by the manufacturer: (i) The test prescribed in § 73.114(b)(1) using seed virus as test material in place of monovalent virus pool material and (ii) the following comparative intramuscular neurovirulence test: Each of at least ten monkeys shall be infected with a total of 5.0 ml. of the seed virus under test if one or

more proximate locations of either a gluteus or gastrocnemius muscle. Similar injections shall be made in another group of ten monkeys using the NIH Reference Attenuated Poliovirus. Each monkey shall be injected intramuscularly with no less than $10^{7.7}$ $TCID_{50}$ of viral inoculum. All monkeys shall be observed for 17 to 21 days and a comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the NIH Reference Attenuated Poliovirus, as prescribed in § 73.114(b)(1)(iii).

(5) Subsequent and identical neurovirulence tests shall be performed in monkeys whenever there is evidence of a change in the neurovirulence of the production virus and upon introduction of a new production seed lot and as often as necessary otherwise to establish to the satisfaction of the Surgeon General that the seed virus strains for vaccine manufacture have maintained their neurovirulence properties as set forth in § 73.114(b)(1).

• • • •

§ 73.114 Test for safety.

• • • •

(b) *Tests after filtration.* The following test relating to safety shall be performed after the filtration process, on each monovalent virus pool or on each multiple thereof (monovalent lot):

(1) *Neurovirulence in monkeys.* Each monovalent virus pool or monovalent lot shall be tested in comparison with the NIH Reference Attenuated Poliovirus for neurovirulence in Macaca monkeys by both the intrathalamic and intraspinal routes of injection. A preinjection serum sample obtained from each monkey must be shown to contain no neutralizing antibody in a dilution of 1:4 when tested against no more than 1,000 $TCID_{50}$ of each of the three types of poliovirus. The neurovirulence tests are not valid unless the sample contains at least $10^{7.0}$ $TCID_{50}$ per ml. when titrated in comparison with the

NIH Reference Poliovirus, Live, Attenuated of the appropriate type. All monkeys shall be observed for 17 to 21 days, under the supervision of a qualified pathologist, physician or veterinarian, and any evidence of physical abnormalities indicative of poliomyelitis or other viral infections shall be recorded.

(i) *Intrathalamic inoculation.* Each of at least ten Macaca monkeys shall be injected intrathalamically with 1.0 ml. of virus pool material containing at least $10^{7.0}$ $TCID_{50}$ per ml. and each of at least ten additional Macaca monkeys shall be injected intrathalamically with 1.0 ml of a 10^{-1} dilution thereof. Comparative evaluations shall be made with the virus pool under test and the NIH reference material. Only monkeys that show evidence of inoculation into the thalamus shall be considered as having been injected satisfactorily.

(ii) *Intraspinal inoculation.* Each of a group of at least five Macaca monkeys shall be injected intraspinally with 0.2 ml. of virus pool material containing at least $10^{7.0}$ $TCID_{50}$ per ml. and each monkey in four additional groups of at least five Macaca monkeys shall be injected intraspinally with 0.2 ml. of 10^{-1}, 10^{-2}, 10^{-3}, and 10^{-4} dilutions thereof, respectively. Comparative evaluations shall be made with the virus pool under test and the NIH reference material. Only monkeys that show microscopic evidence of inoculation into the gray matter of the lumbar cord shall be considered as having been injected satisfactorily.

(iii) *Determination of neurovirulence.* At the conclusion of the observation period comparative histopathological examinations shall be made of the lumbar cord, cervical cord, lower medulla, upper medulla and mesencaphalon of each monkey in the groups injected with virus under test and those injected with the NIH Reference Attenuated poliovirus, except that for animals dying during the test period, these examinations shall be made immediately after death. The animals shall be examined to ascertain whether the distribution and histological nature of the lesions are characteristic of poliovirus infection. A comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the NIH Reference Attenuated Poliovirus with respect to (a) the number of animals showing lesions characteristic of poliovirus infection, (b) the number of animals showing lesions other than those characteristic of poliovirus infection, (c) the severity of the lesions, (d) the degree of dissemination of the lesions, and (e) the rate of occurrence of paralysis not attributable to the mechanical injury resulting from inoculation trauma. The virus pool under test is satisfactory for poliovirus vaccine manufacture only if at least 80 percent of the animals in each group survive the observation period and if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the NIH Reference Attenuated Poliovirus.

• • • •

Title 21 C.F.R. (1978)

Subpart A—Release Requirements

§ 610.1 Tests prior to release required for each lot.

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.

§ 610.2 Requests for samples and protocols; official release.

(a) *General.* Samples of any lot of any licensed product, except for radioactive biological products, together with the protocols showing results of applicable tests, may at any time be required to be sent to the Director, Bureau of Biologics. Upon notification by the Director, Bureau of Biologics, a manufacturer shall not distribute a lot of a product until the lot is released by the Director, Bureau of Biologics: *Provided,* That the Director, Bureau of Biologics, shall not issue such notification except when deemed necessary for the safety, purity, or potency of the product.

* * * *

(b) *Consistency of manufacture.* No lot of vaccine shall be released unless each monovalent pool contained therein is one of a series of five consecutive pools of the same type, each pool having been manufactured by the same procedures, and each having met the criteria of neurovirulence for monkeys prescribed in § 630.16(b)(1), and of in vitro markers prescribed in § 630.16(b)(3).

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No. 87-498

In the Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

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QUESTION PRESENTED

Whether the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. 2680(a), bars petitioners' claims that the government was negligent in its 1963 decision to license production of the Sabin oral polio vaccine and in its subsequent approval of the release of a specific lot of that vaccine.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	1
Statutory provision involved	2
Statement	2
Polio and the Sabin vaccine	2
Facts and proceedings below	5
Summary of argument	9
Argument:	
The discretionary function exception to the Federal Tort Claims Act bars liability based on the alleged negligence of the FDA in carrying out its regulatory task of licensing vaccines and other drugs	12
A. The discretionary function exception bars claims against the government for alleged negligence in the execution of a safety-related regulatory program	15
B. The FDA licensing process is indistinguishable from the FAA certification process for purposes of the discretionary function exception	28
1. The product license	29
2. The lot release	38
C. The national childhood vaccine injury act confirms that Congress did not intend for the FDA to be held liable under the FTCA for injuries caused by vaccines	41
Conclusion	45

TABLE OF AUTHORITIES

Cases: Page

Bacon v. *United States*, 810 F.2d 827 (8th Cir. 1987) 22
Baker v. *United States*, 817 F.2d 560 (9th Cir. 1987) 37
Barnson v. *United States*, 816 F.2d 549 (10th Cir. 1987), cert. denied, No. 87-104 (Oct. 13, 1987) 22
Baxley v. *United States*, 767 F.2d 1095 (4th Cir. 1985) 22, 27
Begay v. *United States*, 768 F.2d 1059 (9th Cir. 1985) 22
Cisco v. *United States*, 768 F.2d 788 (7th Cir. 1985) 22
Collins v. *United States*, 783 F.2d 1225 (5th Cir. 1986) 23, 27
Cunningham v. *United States*, 786 F.2d 1445 (9th Cir. 1986) 22
Dalehite v. *United States*, 346 U.S. 15 (1953) ..... *passim*
Feyers v. *United States*, 749 F.2d 1222 (6th Cir. 1984), cert. denied, 471 U.S. 1125 (1985) 22
General Public Utilities Corp. v. *United States*, 745 F.2d 239 (3d Cir. 1984), cert. denied, 469 U.S. 1228 (1985) 22
Griffin v. *United States*, 500 F.2d 1059 (3d Cir. 1974) 6, 7
Hanberry v. *Hearst Corp.*, 276 Cal. App. 2d 680, 81 Cal. Rptr. 519 (1969) 19
Hatahley v. *United States*, 351 U.S. 173 (1956) 23, 24
Heckler v. *Chaney*, 470 U.S. 821 (1985) 33
Hylin v. *United States*, 755 F.2d 551 (7th Cir. 1985) 22
Kosak v. *United States*, 465 U.S. 848 (1984) 15-16
McMichael v. *United States*, 751 F.2d 303 (8th Cir. 1985) 23
Merklin v. *United States*, 788 F.2d 172 (3d Cir. 1986) 22
National Carriers, Inc. v. *United States*, 755 F.2d 675 (8th Cir. 1985) 23
Natural Gas Pipeline Co. v. *United States*, 742 F.2d 502 (9th Cir. 1984) 22

Cases—Continued: Page

Russell v. *United States*, 763 F.2d 786 (10th Cir. 1985) 22
Shuman v. *United States*, 765 F.2d 283 (1st Cir. 1985) 22
United States v. *Muniz*, 374 U.S. 150 (1963) 21
United States v. *Neustadt*, 366 U.S. 696 (1961) 19
United States v. *S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984) ..... *passim*
United States v. *Spelar*, 338 U.S. 217 (1949) 18
Wendler v. *United States*, 782 F.2d 853 (10th Cir. 1985), cert. denied, 476 U.S. 112 (1986) 22

Statutes and regulations:

Act of July 1, 1902, ch. 1378, 32 Stat. 728 12
§ 4, 32 Stat. 729 13
Act of Mar. 31, 1961, Pub. L. No. 87-14, 75 Stat. 23 5
Administrative Procedure Act, 5 U.S.C. (& Supp. IV) 551 *et seq.* 27
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. (& Supp. IV) 301 *et seq.*:
21 U.S.C. 321(g)(1) 14
21 U.S.C. 351(a)(2)(B) 14
21 U.S.C. 374 20
Federal Tort Claims Act:
28 U.S.C. 1346(b) 15
28 U.S.C. 2674 ..... 15, 16
28 U.S.C. 2680 2
28 U.S.C. 2680(a) 6, 16, 17, 25, 28
28 U.S.C. 2680(a)-(n) 16
28 U.S.C. 2680(h) 19
National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 41
Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330 41
§§ 2110-2111 41
§ 2111(a)(5)(A) 42

Statutes and regulations—Continued: Page

§ 2111(a)(7) 42
§ 2111(c) 42
§ 2112 42
§ 2115 .....
§ 2115(a) 42
§ 2115(d) 42
§ 2115(e) 42
§§ 2115(i)-(j) 41
§ 2117 41
§ 2121 42
§ 2122 42
§ 2134 41

Public Health Service Act, ch. 373, § 351, 58 Stat. 702 12

Vaccination Assistance Act of 1962, Pub. L. No. 87-868, 76 Stat. 1155:

42 U.S.C. 247b 5
42 U.S.C. (1976 ed.) 247b(j)-(*l*) 44
42 U.S.C. (1976 ed.) 247b(k)(2) 44

7 U.S.C. 77 20
7 U.S.C. 136g 20
7 U.S.C. 150ff 20
12 U.S.C. 1817 20
15 U.S.C. 1401 21
15 U.S.C. 2053(h) 44
15 U.S.C. 2065 21
18 U.S.C. (Supp. IV) 923(g) 21
21 U.S.C. 44 21
21 U.S.C. 603(a) 20
21 U.S.C. 693 20
28 U.S.C. 1292(b) 7
29 U.S.C. 657 20
30 U.S.C. 813 20
33 U.S.C. 467a 21
33 U.S.C. 1318 20
33 U.S.C. 1512 21
38 U.S.C. 642 21
42 U.S.C. 262 13
42 U.S.C. 262(a) 12

Statutes and regulations—Continued: Page

42 U.S.C. 262(d) 8, 13
42 U.S.C. 1472 20
42 U.S.C. 2201(*o*) 20
42 U.S.C. 5413 21
42 U.S.C. (& Supp. III) 6927 20
45 U.S.C. 23 20
16 C.F.R.:

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In the Supreme Court of the United States

OCTOBER TERM, 1987

No. 87-498

KEVAN BERKOVITZ, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-27a) is reported at 822 F.2d 1322. The opinion of the district court (Pet. App. 28a-36a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on June 30, 1987. The petition for a writ of certiorari was filed on September 25, 1987, and was granted on January 11, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISION INVOLVED

28 U.S.C. 2680 provides, in pertinent part:

> The provisions of this chapter and section 1346(b) of this title shall not apply to—
>
> (a) Any claim * * * based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.
>
> * * * * *

STATEMENT

Polio and the Sabin Vaccine

Prior to 1955, poliomyelitis was a major crippler of children in the United States and throughout the world. In 1952 alone, 57,879 cases of polio were reported in the United States, of which 21,269 cases resulted in crippling paralysis to the victims. See 77(12) *Pub. Health Rep.* 1011-1020 (1962).[1] The first major step in the eradication of polio came with the development of the Salk inactivated-virus vaccine, which was licensed in this country in 1955.[2] The Salk vaccine immediately regis-

[1] Polio is caused by an enterovirus that is introduced into the body orally and begins to reproduce rapidly in the intestinal tract. In only about one percent of cases will this original "infection" result in clinical symptoms of poliomyelitis. When the disease does result, it is caused by a spread of the virus from the intestinal tract to the brain and spinal column, where it causes damage to the nervous system, resulting in the characteristic muscular paralysis. See J. Melnick, *"Enteroviruses,"* in *Viral Infections of Humans* 217-218, 220 (A. Evans 2d ed. 1982).

[2] Salk vaccine is a killed virus vaccine produced by growing the virus in a tissue culture and killing it chemically to render it incapable of replicating and thereby causing disease, but capable of acting as an antigen to stimulate the production of antibodies. If a wild or virulent strain of poliovirus subsequently enters the body, the antibodies will block the live virus and prevent the contraction of polio. J. Melnick, *supra*, at 228.

tered great progress against the disease, but it was not a perfect solution. A 1962 Report of the Surgeon General recognized that "extensive use of the Salk-type, killed-virus vaccine during the past seven years has greatly lowered the incidence of paralytic disease but has not prevented either sporadic cases or occasional epidemics in highly-vaccinated communities." HEW, *Revised Recommendations and Report: The Surgeon General's Advisory Committee on Poliomyelitis Control* 1 (Feb. 17, 1962) [hereinafter *Surgeon General Report*]. After a record low of 2,499 cases of paralytic polio in 1957, the number of cases began to increase and had more than doubled to 6,289 in 1959. Moreover, data regarding antibody levels 2 to 4 years after inoculation with the Salk vaccine indicated that repeated, possibly frequent, booster shots would be required for an individual to retain immunity. *Report of Committee on Infectious Diseases*, Am. Acad. of Pediatrics 47 (1966) [hereinafter *Infectious Diseases Report*].

The second major breakthrough in combating the disease occurred with the development of the Sabin oral polio vaccine which was introduced here in the early 1960s. Unlike the Salk vaccine, the oral vaccine contains a weakened, but live, polio virus. The Sabin vaccine offered several advantages over the Salk vaccine. First, it induces effective, lasting immunization without need of subsequent booster shots. Second, it can be administered with comparative ease, since it is taken orally instead of by injection. Third, it protects against infection as well as disease, thereby insuring that infected persons would not become transmitters of the wild poliovirus. Finally, and of particular importance, the virus in the Sabin vaccine is also communicated to persons in close contact with the vaccinee. By this means, individuals not directly reached through the vaccination program nevertheless receive the benefits of immunization. See *Infectious Diseases Report* 47-48. Because of these advantages, the Sabin vaccine rapidly displaced the Salk vaccine in the

early 1960s. It became "the vaccine of choice for community-wide vaccination programs and for routine immunization in infancy and childhood" (*id.* at 48). See *Surgeon General Report* 1. By the mid-1970s, the total number of cases of paralytic polio reported in the United States had declined to approximately ten to twenty per year. See Center for Disease Control, 28(54) *Morbidity and Mortality Weekly Report* 12 (Nov. 16, 1984). Current figures reveal an annual average of ten cases. Nkowane & Wassilak, *et al.*, *Vaccine-Associated Paralytic Poliomyelitis, United States: 1973 Through 1984*, 257(10) J. Am. Med. A. 1335 (Mar. 13, 1987).

Despite this record of success, there has been continued debate over the relative merits of the Salk and Sabin vaccines. See, *e.g.*, Boffey, *Polio: Salk Challenges Safety of Sabin's Live-Virus Vaccine*, 196 Science 35 (1977). It has been determined that the Sabin vaccine creates a very slight risk that the vaccinee or someone in close contact with him will contract the disease.[3] No similar risk exists with the Salk vaccine, provided the virus used in the vaccine is successfully killed. After exhaustive study, however,[4] the

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[3] There is a very slight risk that paralytic poliomyelitis may be contracted by persons who ingest the Sabin oral polio vaccine, or by persons coming in close contact with the vaccinee. Between 1972 and 1983, 87 vaccine-associated cases in apparently immunologically normal individuals were reported. During that period, 278.8 million OPV (oral polio vaccine) doses were distributed in the United States. Thirty-two vaccine-associated cases of poliomyelitis occurred among vaccine recipients (one case per 8.7 million OPV doses distributed) and 55 cases occurred among household and non-household contacts of vaccinees (one case per 5.1 million doses distributed).

Center for Disease Control, 33(45) *Morbidity and Mortality Weekly Report: Paralytic Poliomyelitis—United States, 1982 and 1983*, at 637 (Nov. 16, 1984).

[4] See, *e.g.*, Nightengale, *Recommendations for a National Policy on Poliomyelitis Vaccination*, 297 New Eng. J. Med. 249-253 (1977)

United States remains firmly committed to the Sabin vaccine.[5]

Facts and Proceedings Below

1. Petitioner Kevan Berkovitz contracted polio in June 1979 shortly after receiving Orimune, a Sabin oral polio vaccine manufactured by Lederle Laboratories. Berkovitz, joined by his parents as guardians, filed suit in federal district court in December 1984 alleging that the United States was liable for his injuries under the Federal Tort Claims Act (FTCA) because the government was negligent in licensing Orimune on June 25, 1963, and because the Food and Drug Administration (FDA) was negligent in releasing the specific lot of vaccine from which Berkovitz received his dose on May 10, 1979 (Pet. App. 4a).[6] As to the first claim, petitioners alleged that the Division of Biologic Standards (DBS), at that time part of the National Institutes of Health, issued a license for Lederle's Sabin poliovirus strain when it had not been

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(reporting results of study by Institute of Medicine of the National Academy of Sciences commissioned by HEW); Center for Disease Control, 26(40) *Morbidity and Mortality Weekly Report: Recommendation of the Public Health Service Advisory Committee on Immunization Practices* 329 (Oct. 7, 1977); *id.* 31(3) *Morbidity and Mortality Weekly Report: 1982 ACIP Report* 22 (Jan. 29, 1982).

[5] Congress has actively promoted use of the Sabin vaccine since 1961 when it appropriated $1 million for a stockpile of the newly-developed vaccine to be used in combatting epidemics. Act of Mar. 31, 1961, Pub. L. No. 87-14, 75 Stat. 23. In the Vaccination Assistance Act of 1962 Congress launched mass immunization campaigns using the Sabin vaccine. Pub. L. No. 87-868, 76 Stat. 1155. Although Congress originally envisioned an intensive three-year effort, the need for ongoing federal support for immunization programs became apparent and continues to be provided through the Act, now codified at 42 U.S.C. 247b. All fifty states and the District of Columbia require vaccination before a child enters school.

[6] Petitioners also sued Lederle Laboratories in a separate civil action. That suit was settled shortly before the instant case was filed. Pet. App. 5a n.3. See *Berkovitz* v. *Lederle*, No. GD 80-28592 (Alleghany County C.P. Ct. filed Nov. 17, 1980). The terms of the settlement are under seal.

tested in accordance with DBS's own regulations, and that DBS failed to require Lederle to show that a particular "seed virus" had been subjected to all required testing and had complied with all regulatory standards. Br. 4-6; Pet. App. 4a-5a. On the second issue, petitioners claimed that the Bureau of Biologics of the FDA improperly issued a lot release approval, permitting the vaccine containing Berkovitz's dose to be distributed to the public, despite the fact that the virus in the vaccine had been tested and found to exceed the standards for neurovirulence set forth in regulations applicable to live polio vaccines. Br. 6-7, 20-21; Pet. App. 4a-5a.[7]

2. The government moved to dismiss the suit as barred by the discretionary function exception to the FTCA, 28 U.S.C. 2680(a). The district court (Pet. App. 28a-36a) agreed that the government was immune from two of petitioners' original claims,[8] but nonetheless concluded that both the licensing of Lederle to produce the vaccine and the release of the specific vaccine lot were not "discretionary function[s]" within the meaning of the FTCA (*id.* at 33a). The district court noted that the Third Circuit had already held in *Griffin v. United States*, 500 F.2d 1059 (1974), that negligent release of a noncomplying lot of polio vaccine was not a discretionary function. The government maintained in its motion to dismiss that *Griffin* had been effectively overruled by

[7] Petitioners also claimed in district court that the United States was negligent in failing to withdraw the vaccine from the market and in failing to require the manufacturer to provide adequate warnings. These allegations were dismissed in the district court as barred by the FTCA's "discretionary function" exception (Pet. App. 33a), and petitioners conceded the propriety of that dismissal on appeal (*id.* at 6a n.4). The petition for a writ of certiorari did not ask this Court to review those issues (see Pet. 3-5). Without acknowledging their prior concession, in their Brief on the Merits (at 6, 19-20) petitioners once again argue that the government is liable for failing to revoke Lederle's license and withdraw the vaccine from the market.

[8] See note 7, *supra*.

this Court's decision in *United States* v. *S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984). The district court declined to consider the effect of *Varig Airlines*, however, noting that, as a reported decision of the Third Circuit, *Griffin* was binding on the district courts in that circuit "no matter how persuasive the arguments may be that *Griffin* is no longer valid" (Pet. App. 33a).

3. At the government's request, the district court certified its decision for immediate appeal to the Third Circuit pursuant to 28 U.S.C. 1292(b), which reversed in a divided opinion (Pet. App. 1a-27a). The court of appeals initially rejected the government's argument that the discretionary function exception bars all claims arising out of the regulatory activities of federal agencies (*id.* at 12a-15a). Concluding that it "need not treat separately the licensing claim and the lot release claim" (*id.* at 15a), the court then proceeded to analyze the question whether the government had a nondiscretionary duty to ensure that Lederle followed regulatory standards in the production and distribution of the Sabin polio vaccine (*ibid.*).

The court of appeals canvassed the applicable regulations and noted that, while they required the manufacturer to perform certain tests and submit qualifying results to the government, they did not require the government to do anything (Pet. App. 16a-18a). The court concluded that, as in *Varig Airlines*, the onus was on the manufacturer to comply with applicable safety standards, while the role of the government agency was "'merely to police the conduct of private individuals by monitoring their compliance with [the applicable] regulations'" (*id.* at 22a (quoting 467 U.S. at 815)). See Pet. App. 16a ("the safety regulations governing live polio vaccine leave at least as much enforcement discretion to the FDA as the regulations at issue in *Varig* left to the FAA").

The court of appeals also examined the statutory requirement that licenses may be issued "only upon a showing that * * * the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations" (42 U.S.C. 262(d)). The court rejected the dissent's contention that this statute created a nondiscretionary duty for the FDA "to 'insure' compliance with its safety regulations" (Pet. App. 18a).[9] "[T]he FDA's statutory duty," the court concluded, "is not different in substance from the duty that the Supreme Court in *Varig* found rests with the FAA" (*ibid.*). In both cases, the agency is left with a policy choice as to how to construct and implement a mechanism for compliance review. Because "neither the statute nor the regulations mandate the FDA's choice of how to secure Lederle's compliance" (*id.* at 22a), the court concluded that the discretionary function exception bars suit for alleged negligence in the government's performance of that role.

The court of appeals acknowledged that the allegations in this case differ from those in *Varig Airlines* in that petitioners here claimed that "the FDA exercised its discretion to verify compliance and then negligently erred in finding compliance" (Pet. App. 20a). Petitioners argued that "once the FDA had information that the vaccine did not comply with the regulations, it had no discretion to approve either the license for production or the

[9] Judge Higginbotham, in his dissenting opinion (Pet. App. 25a), argued that 42 U.S.C. 262(d) "creates a governmental duty not to license a manufacturer that has shown the government that its vaccine is defective." He compared the FDA's mandate with the statutes governing the FAA, which he said "are not commands at all." "Rather," the dissent argued (Pet. App. 26a (emphasis in original)), "they amount to requests for the prudent exercise of agency discretion, and they are *truly* different in substance from the statute that *prohibits* vaccine licensure by the government whenever the requisite showing has not been made."

lot for release" (*ibid.*). But the court noted that "this argument is simply that the FDA acted negligently" and "the issue of negligence is not relevant to the discretionary function inquiry" (*id.* at 21a (citation and quotation marks omitted)).

The FDA made a policy choice to attempt to monitor compliance by manufacturers more closely than the "spot-check" review conducted by FAA. But that policy choice does not subject an agency to liability for "negligently fail[ing] to recognize and remove noncomplying products" (Pet. App. 21a). An alternative holding, the court stated, "would inhibit the agency's selection of the mechanism for compliance review" and "[t]his is precisely what *Varig* instructs us not to do" (*ibid.*). "It follows," the court concluded, "that when the FDA makes the discretionary choice to examine or test samples which it has discretion not to test, it cannot be held liable for subsequent negligence at the operational level in implementing its decision to test" (*ibid.*).

SUMMARY OF ARGUMENT

The Food and Drug Administration (FDA) has a general mandate to construct and implement a licensing program for vaccines and other prescription drugs. Its role is two-fold: it fashions standards of safety, potency and purity that any such product must meet and it polices compliance with those standards through licensing and inspections. As with other regulatory programs, however, the primary burden of compliance with FDA regulations (and, consequently, any responsibility for noncompliance) rests upon the manufacturer. The FDA's activities as a policeman of private conduct are accordingly protected from suit by the discretionary function exception to the FTCA. As this Court noted in *Varig Airlines*, 467 U.S. at 821, regulatory agencies have "a statutory duty to *promote* safety" in the industries they regulate, "not to insure it."

Petitioners contend that when licensing and inspection activities are governed by mandatory regulations and an agency negligently violates its own regulations in issuing a license or conducting an inspection, the discretionary function exception does not apply. There are three related flaws in this argument. First, it ignores the wording of the discretionary function exception, which protects agency *functions*, not individual acts, and which precludes liability whether or not the government has acted negligently by breaching one of its own regulations. The FDA's "implementation of a mechanism for compliance review is plainly discretionary activity of the 'nature and quality' protected by § 2680(a)" (*Varig Airlines*, 467 U.S. at 819), and the discretionary function exception shields from liability "both negligence and wrongful acts in the exercise of discretion." *Dalehite* v. *United States*, 346 U.S. 15, 33 (1953). Second, it largely eliminates the protection of regulatory functions—thereby frustrating the prime motivation for the discretionary function exception—because tort claims can almost always be couched in terms of mandatory duties left unperformed. What was intended as a bar to suit would become merely a rule of pleading. Third, contrary to Congress's express intention, it interjects tort considerations into a regulatory agency's fundamental policy decision on how specifically to write its regulations (and, hence, how carefully to regulate private industry) by providing agencies with a strong incentive towards vagueness and a lack of guidelines for inspectors. "When an agency determines the extent to which it will supervise the safety procedures of private individuals, it is exercising discretionary regulatory authority of the most basic kind." *Varig Airlines*, 467 U.S. at 819-820.

As a general principle, therefore, safety-related licensing and inspection activities are shielded from suit by the discretionary function exception regardless of claims that the agency in question has violated its own regulations. In any event, petitioners are unsuccessful in their

attempt to portray the FDA's regulations as imposing mandatory duties on FDA employees. In fact, the burden of compliance in each instance cited by petitioners is placed squarely on the private manufacturer. The regulations require the manufacturer to perform certain tests and submit qualifying data to the FDA prior to using a particular seed virus in its vaccine or prior to releasing a lot of vaccine. But the regulations impose no duties on the FDA to perform any tests on its own; nor do the regulations indicate the extent to which FDA must review the data submitted to ensure compliance. A decision to redo certain tests or examine certain test results is clearly "discretionary regulatory authority of the most basic kind" (*Varig Airlines*, 467 U.S. at 820). Petitioners claim that the FDA performed this function negligently, thereby permitting release of a noncomplying lot; but clearly the discretionary function exception bars suit for alleged "negligence and wrongful acts in the exercise of the discretion" (*Dalehite*, 346 U.S. at 33). Thus, "when the FDA makes the discretionary choice to examine or test samples which it has discretion not to test, it cannot be held liable for subsequent negligence at the operational level in implementing its decision to test" (Pet. App. 21a).

The FDA has not been delegated any authority by Congress to turn itself into an insurer of the industry it regulates. Congress knows how to set up an insurance program for a regulated industry when it wants to, and when it does so the program looks very different from an ordinary regulatory scheme. We know that because in 1986 Congress passed just such a program in the National Childhood Vaccine Act of 1986. The Act establishes a National Vaccine Injury Compensation Program that is intended to provide an exclusive remedy for vaccine-related injuries. An essential premise of that program is that persons injured by vaccines have no tort remedy against the United States for licensing the vaccines. For the Court now to overlay this insurance scheme with tort liability under the FTCA would wholly

disrupt the compensation scheme in the Act as well as Congress's attempt to fund the program with a minimum drain on the public fisc.

ARGUMENT

THE DISCRETIONARY FUNCTION EXCEPTION TO THE FEDERAL TORT CLAIMS ACT BARS LIABILITY BASED ON THE ALLEGED NEGLIGENCE OF THE FDA IN CARRYING OUT ITS REGULATORY TASK OF LICENSING VACCINES AND OTHER DRUGS

No biological product "applicable to the prevention, treatment, or cure of diseases or injuries of man" may be sold in the United States that has not been "propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary [of Health and Human Services] as hereinafter authorized, to propagate or manufacture, and prepare such" product (42 U.S.C. 262(a)). This federal regulation of vaccines and other biological products for human use was first enacted in 1902, Act of July 1, 1902, ch. 1378, 32 Stat. 728, and later revised in 1944 as part of the recodification of the Public Health Service Act, ch. 373, § 351, 58 Stat. 702.

The Act of July 1, 1902 did not specify any standards to govern the licensing of biological products (which, under the Act, was the ultimate responsibility of the Secretary of the Treasury).[10] The Act simply provided that "the Surgeon-General of the Army, the Surgeon-General

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[10] For 46 years, the biologics control program operated under the immediate supervision of the director of the Hygenic Laboratory and its successor, the National Institutes of Health (NIH). In 1948 it was made a part of the National Microbiological Institute, a unit of NIH. In 1955, the Division of Biologics Standards (DBS) was established within NIH. DBS was then transferred from NIH to the FDA in 1972 and renamed the Bureau of Biologics. See 37 Fed. Reg. 12865 (1972).

of the Navy, and the supervising Surgeon-General of the Marine-Hospital Service, be, and they are hereby, constituted a board with authority, subject to the approval of the Secretary of the Treasury, to promulgate from time to time such rules as may be necessary in the judgment of said board to govern the issue, suspension, and revocation of licenses for the maintenance of establishments for the propagation and preparation of viruses, serums, toxins, antitoxins, and analogous products, applicable to the prevention and cure of diseases of man" (§ 4, 32 Stat. 729). In 1944 Congress offered more specific guidance (42 U.S.C. 262(d)):

> Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations * * *.

Petitioners and the dissent below argue that this statutory language imposes a "non-discretionary" duty on the FDA to *guarantee* compliance by manufacturers with all regulatory standards prior to issuing a license (see Br. 15-16, 19; Pet. App. 25a-26a). This argument is clearly untenable. Section 262 is simply a general mandate to construct a regulatory licensing program. In supporting enactment of the section, the Committee Report to the Public Health Act explained that "Subsection (d) would furnish criteria, not expressed in the present law, to *guide* administrative action in the issuance of licenses." H.R. Rep. 1364, 78th Cong., 2d Sess. 23 (1944) (emphasis added). Congress thus established the general areas—

"safety, purity, and potency"—within which the FDA was to promulgate regulations for biological products.[11] But the precise nature of those regulations and, hence, the standards for safety, purity and potency as well as the manner in which a manufacturer may demonstrate compliance with the standards was left completely to the discretion of the agency. Like the regulatory scheme at issue in *Varig*, the FDA's choice and "implementation of a mechanism for compliance review is plainly discretionary activity of the 'nature and quality' protected by § 2680(a)." *Varig Airlines*, 467 U.S. at 819. The court of appeals therefore correctly concluded that the FDA's statutory instruction to establish standards and police compliance, like the analogous statute considered in *Varig Airlines*, is not "the type of mandate that makes the discretionary function analysis inapplicable" (Pet. App. 20a).

The statute itself therefore does not deny the FDA discretion in determining whether to license Lederle to produce the Sabin vaccine. Petitioners accordingly devote the bulk of their brief to their contention that the regulations promulgated by the FDA create a mandatory, nondiscretionary duty on the part of FDA employees to ensure compliance with the standards contained therein. It is our contention that the FDA regulations governing the oral polio vaccine, like the FAA regulations at issue in *Varig Airlines*, place no such mandatory duty on the regulating agency. In both cases the ultimate burden of compliance rests with the manufacturer, and the regulations create no duty enforceable against the agency by a tort action. We believe that this is demonstrable by reference to the particular regulations in issue (see pp.

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[11] Vaccines are also classified as prescription drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), and are, thus, subject to certain provisions of that Act as well. See, *e.g.*, 21 U.S.C. 351(a)(2)(B) (conformity with current good manufacturing practice).

28-40, *infra*). More generally, however, we submit that the discretionary function exception bars any and all claims against the government for alleged negligence in the implementation of a safety-related regulatory program.

A. The Discretionary Function Exception Bars Claims Against The Government For Alleged Negligence In The Execution Of A Safety-Related Regulatory Program

1. The FTCA waived the sovereign immunity traditionally enjoyed by the United States against tort suits. See 28 U.S.C. 1346(b) and 2674. This waiver of immunity was considered to be a "radical innovation," however, prompting Congress to move cautiously. *Tort Claims Against the United States: Hearings on H.R. 7236 Before Subcomm. No. 1 of the House Comm. on the Judiciary*, 76th Cong., 3d Sess. 22 (1940). Congress only wanted to make the federal government amenable to suit for "ordinary common-law torts." *Dalehite*, 346 U.S. at 28 (footnote omitted). The legislative history of the FTCA, therefore, is substantially devoted to discussions regarding the need to supply a judicial remedy for automobile accidents involving government employees who drive negligently in the course of their employment.[12] See *Kosak* v. *United States*, 465 U.S. 848, 855 (1984)

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[12] See, *e.g.*, 67 Cong. Rec. 11092, 11100 (1926) (remarks of Reps. Celler, Underhill); 69 Cong. Rec. 2192, 3118 (1928) (remarks of Reps. Lozier, Box); *General Tort Bill: Hearings Before a Subcomm. of the House Comm. on Claims*, 72d Cong., 1st Sess. 17 (1932); *Tort Claims Against the United States: Hearings on H.R. 7236 Before Subcomm. No. 1 of the House Comm. on the Judiciary*, 76th Cong., 3d Sess. 16 (1940); *Tort Claims Against the United States: Hearings on S. 2690 Before a Subcomm. of the Senate Comm. on the Judiciary*, 76th Cong., 3d Sess. 27-28 (1940); *Tort Claims: Hearings on H.R. 5373 and H.R. 6463 Before the House Comm. on the Judiciary*, 77th Cong., 2d Sess. (1942); H.R. Rep. 2245, 77th Cong., 2d Sess. 10 (1942); H.R. Rep. 1287, 79th Cong., 1st Sess. 5 (1945); S. Rep. 1400, 79th Cong., 2d Sess. 31 (1946). The Federal

(footnote omitted) ("One of the principal purposes of the Federal Tort Claims Act was to waive the Government's immunity from liability for injuries resulting from auto accidents in which employees of the Postal Service were at fault.").

Congress did not intend to extend the FTCA to suits against the United States based on "that class of tort on the part of the Government which has to do with a governmental function, so to speak." 86 Cong. Rec. 12021 (1940) (remarks of Rep. Gwynne). Accordingly, Congress placed a number of significant limitations on the types of tort suits that could be brought against the United States. See 28 U.S.C. 2680(a)-(n). "One only need read § 2680 in its entirety to conclude that Congress exercised care to protect the Government from claims, however negligently caused, that affected the governmental functions." *Dalehite*, 346 U.S. at 32. See *Kosak* v. *United States*, 465 U.S. at 858 (one of the principal objectives of the enumerated exceptions in Section 2680 was "ensuring that 'certain governmental activities' not be disrupted by the threat of damages suits").[13]

The most important (see H.R. Rep. 1287, 79th Cong., 1st Sess. 5-6 (1945)) of the limitations on the types of torts suits that may be brought against the United States is that embodied in 28 U.S.C. 2680(a), barring actions "based upon the exercise or performance or the

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Tort Claims Act was adopted in 1946 after more than 20 years of congressional consideration. This Court has recognized that legislative statements made with regard to earlier versions of the FTCA are useful in understanding the meaning of the Act as eventually passed. *Varig Airlines*, 467 U.S. at 808-810; *Dalehite*, 346 U.S. at 26-30.

[13] Comparable, and overlapping, protection against damage liability for engaging in core governmental activities was provided by Congress in 28 U.S.C. 2674, which states that the United States may be liable only "in the same manner and to the same extent as a private individual under like circumstances."

failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." This "discretionary function exception," as it is commonly called, "marks the boundary between Congress' willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals." *Varig Airlines*, 467 U.S. at 808.

The boundary is not always clearcut. Where direct government conduct is in issue—as where the government produces a product (*e.g.*, a bridge built by the Army Corps of Engineers) or provides a service (*e.g.*, fire fighting by the Forest Service), the negligent performance of that conduct may bring about injuries that would be actionable under state law if similarly caused by a private person. Where such actions flow from discretionary policy judgments, however, they are immune from FTCA attack under the discretionary function exception. *Dalehite*, 346 U.S. at 35-36. The precise limits of that protection are not susceptible to easy definition, and this Court has generally avoided speaking in broad terms. *Varig Airlines*, 467 U.S. at 813; *Dalehite*, 346 U.S. at 35-36.

The Court has, however, indicated that where the government is not the primary actor, but acts as a regulator of private conduct, demanding compliance with regulatory standards, the discretionary function exception precludes liability altogether. In *Dalehite*, the Court referred to Section 2680(a) simply as "the governmental regulatory function exception from suits" (346 U.S. at 26). The dissent in *Dalehite* was even more emphatic in stressing that "what was meant [by the exception] is the type of discretion which government agencies exercise in regulating private individuals" (346 U.S. at 58 n.12 (Jackson, J., dissenting)). And in *Varig Airlines*, 467 U.S. at 813-814, the Court noted that "whatever else the discretionary function exception

may include, it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals." [14]

Indeed, protection for regulatory activities seems to have been the prime motivation of Congress in creating this exception. The FTCA was the product of more than two dozen different bills introduced since 1923. See *United States* v. *Spelar*, 338 U.S. 217, 219-220 (1949). Many of the earlier bills contained specific exceptions from liability that "were couched in terms of specific spheres of federal activity, such as postal service, the activities of the Securities and Exchange Commission, or the collection of taxes." *Dalehite*, 346 U.S. at 26 (footnote omitted). See, *e.g.*, Section 303(7) of S. 2690, 76th Cong., 1st Sess. (1939) and Section 303(7) of H.R. 5299, 77th Cong., 1st Sess. (1941) (exempting claims arising from enforcement activities of the Federal Trade Commission and the Securities Exchange Commission). The 77th Congress—in whose work the meaning of the exception "shows most clearly" (*Dalehite*, 346 U.S. at 26)—removed the exemptions granted to specific agencies and expanded the exception to include all discretionary functions. *Varig Airlines*, 467 U.S. at 809.

[14] Petitioners read this sentence (Br. 29-30) as a mere tautology, stating that regulatory acts are covered by the discretionary function exception whenever they are discretionary. But there is no reason to think that the Court intended to add nothing by this sentence. Indeed, as support for the proposition that regulation is inherently a discretionary function, the Court in *Varig* noted that "[e]ven the dissenters in *Dalehite* read the legislative history of the discretionary function exception as protecting 'that type of discretion which government agencies exercise in regulating private individuals.'" 467 U.S. at 814 n.11 (quoting *Dalehite*, 346 U.S. at 58 n.12 (Jackson, J., dissenting)). Furthermore, petitioners' reading is belied by the very next sentence, in which the Court stressed that "[t]ime and again the legislative history refers to the acts of regulatory agencies as examples of those covered by the exception * * *." See also 467 U.S. at 814 n.11 (noting the legislative history's "emphasis upon protection for regulatory activities").

Congress made the change with the declared intent to bar all claims against federal agencies growing out of their regulatory activities. "It was considered unnecessary to except by name such agencies as the Federal Trade Commission and the Securities and Exchange Commission, as had earlier bills, because the language of the discretionary function exception would 'exemp[t] from the act claims against Federal agencies *growing out of their regulatory activities.*'" *Varig Airlines*, 467 U.S. at 810 (quoting from Staff of the House Comm. on the Judiciary, 77th Cong., 2d Sess., *Federal Tort Claims Act, Memorandum, With Appendices, Explanatory of Comm. Print of H.R. 5373*, at 8 (Comm. Print 1942) (emphasis added by Court)).

The rationale for this protection for regulatory functions is two-fold. First, the actions of a government agency in enforcing health and safety legislation pursuant to a program of inspection and licensure have no counterpart in the private sector. Unlike private testing laboratories, which certify the quality of a product at the request and for the benefit of a particular consumer,[15] the government inspects and licenses or certifies for the purpose of protecting the general public by eliminating defective or dangerous instrumentalities from the channels of interstate commerce. Thus, government regulation of private industry is precisely the sort

[15] See generally Note, *Liability of Certifiers of Quality to Ultimate Consumers*, 36 Notre Dame Law. 176, 183 (1961); Note, *Tort Liability of Independent Testing Agencies*, 22 Rutgers L. Rev. 299, 325-326 (1968); Note, *Liability of a Testing Company to Third Parties*, 1964 Wash. U.L.Q. 77, 96-97. Some states have concluded that such laboratories may be liable for negligently certifying the safety of a product. See, *e.g.*, *Hanberry* v. *Hearst Corp.*, 276 Cal. App. 2d 680, 683, 81 Cal. Rptr. 519, 521 (1969). The basis for such liability, however, is negligent misrepresentation, which is expressly excluded from the waiver of sovereign immunity in 28 U.S.C. 2680(h). See *United States* v. *Neustadt*, 366 U.S. 696 (1961).

of core governmental function for which Congress expressly intended to preserve immunity.

Second, the potential liability of the United States for failure to uncover defects or improprieties pursuant to regulatory inspections is staggering. Numerous agencies of the federal government have inspection and/or licensing authority and virtually every business that engages in interstate commerce is subject to some form of federally-administered licensing or certification requirement. To name just a few, the Nuclear Regulatory Commission inspects nuclear reactors (42 U.S.C. 2201(*o*)), the FDA inspects and certifies the safety of food as well as drugs (21 U.S.C. 374), the Federal Deposit Insurance Corporation inspects the financial records of federally-insured banks (12 U.S.C. 1817), the Occupational Safety and Health Administration inspects the safety and health conditions of most work environments (29 U.S.C. 657), and the Mine Safety and Health Administration inspects the safety and health conditions of mines (30 U.S.C. 813).[16] It is implausible in the extreme that Con-

[16] Of course, the list in the text only touches the surface. A cursory examination of the regulatory activities of several government agencies reveals an extraordinary array of inspection and licensing/certification activities. See, *e.g.*, 42 U.S.C. 1472 (Farmers Home Administration inspects homes built with financial assistance provided by the agency); 7 U.S.C. 77 (Department of Agriculture inspects poultry products); 21 U.S.C. 603(a) (Department of Agriculture inspects "all cattle, sheep, swine, goats, horses, mules and other equines" before slaughtering, packing or meat-canning); 7 U.S.C. 150ff (Department of Agriculture inspects for plant pests persons or articles transported into this country); 21 U.S.C. 693 (Department of Agriculture inspects and certifies dairy products intended for export); 33 U.S.C. 1318 (Environmental Protection Agency inspects premises where work with chemical substances is performed); 7 U.S.C. 136g (Environmental Protection Agency inspects establishments where pesticides are distributed or sold); 42 U.S.C. (& Supp. III) 6927 (Environmental Protection Agency inspects hazardous waste facilities); 45 U.S.C. 23 (Department of Transportation inspects locomotives); 15 U.S.C. 1401 (Department of Transportation inspects facilities manufacturing or introducing motor vehicles into commerce, see 49 C.F.R. 554.1 *et seq.*); 33 U.S.C. 1512 (Department of Transportation inspects deepwater ports); 33 U.S.C. 467a (Department of Army inspects dams); 38 U.S.C. 642 (Veterans Administration inspects state nursing care homes); 18 U.S.C. (Supp. IV) 923(g) (Department of Treasury inspects firearms or ammunition kept by importers, manufacturers, dealers and collectors); 21 U.S.C. 44 (Department of Health and Human Services inspects teas entering the United States); 15 U.S.C. 2065 (Consumer Product Safety Commission inspects establishments manufacturing, holding or transporting consumer products in commerce, see 16 C.F.R. 118.1 *et seq.* (1982), 16 C.F.R. 1605.1 *et seq.*); and 42 U.S.C. 5413 (Department of Housing and Urban Development inspects the construction of mobile homes).

gress, while enacting the FTCA with an intention to proceed cautiously and protect from suit certain core governmental functions, meant to waive sovereign immunity for claims based on such administrative inspection and licensing activities.[17]

2. In *Varig Airlines*, the plaintiffs sought to hold the United States liable for alleged negligence of the FAA in inspecting airplanes to check compliance with regulatory standards. This Court held that the FAA's program of conducting safety inspections, with the primary burden placed on the manufacturer to ensure compliance, "falls squarely within the discretionary function exception" (467 U.S. at 820). "By fashioning an exception for discretionary governmental functions," the Court stated, "including regulatory activities, Congress took 'steps to protect the Government from liability that would seriously handicap efficient government operations.'" *Id.* at 814 (quoting *United States* v. *Muniz*, 374 U.S. 150, 163 (1963)).

The principal lesson of *Varig Airlines* is that federal regulatory agencies have "a statutory duty to *promote*

[17] Needless to say, not a word in the voluminous legislative history of the FTCA supports such a result. Compare *Muniz*, 374 U.S. at 153-158.

safety" in the industries they regulate, "not to insure it" (467 U.S. at 821 (emphasis in original)). Most courts have heeded this Court's injunction not to turn agency efforts to enhance safety into government insurance of regulated industries.[18] Several cases decided after *Varig Airlines*, however, have imposed liability on the govern-

[18] See, *e.g.*, *Barnson* v. *United States*, 816 F.2d 549 (10th Cir. 1987) (alleged failure of Public Health Service and AEC to warn uranium miners of, and protect them against, radiation hazards), cert. denied, No. 87-104 (Oct. 13, 1987); *Bacon* v. *United States*, 810 F.2d 827 (8th Cir. 1987) (alleged failure of HUD and EPA to warn of dioxin levels during repair of roads at Times Beach under federal block grant); *Merklin* v. *United States*, 788 F.2d 172 (3d Cir. 1986) (AEC inspectors' alleged failure to warn uranium processing plant employees of health hazards discovered during AEC inspections); *Cunningham* v. *United States*, 786 F.2d 1445 (9th Cir. 1986) (alleged failure of OSHA to exercise reasonable care in conducting plant inspections); *Wendler* v. *United States*, 782 F.2d 853 (10th Cir. 1985) (FAA emergency suspension of commercial pilot's certificate), cert. denied, 476 U.S. 112 (1986); *Begay* v. *United States*, 768 F.2d 1059 (9th Cir. 1985) (alleged failure by federal agencies to warn of dangers of uranium mining); *Cisco* v. *United States*, 768 F.2d 788 (7th Cir. 1985) (EPA's alleged failure to warn that dirt contaminated with dioxin had been used in residential land fill); *Baxley* v. *United States*, 767 F.2d 1095 (4th Cir. 1985) (FAA's allegedly negligent decision not to regulate or inspect ultralite aircraft); *Shuman* v. *United States*, 765 F.2d 283 (1st Cir. 1985) (alleged negligence by Navy in not controlling use and handling of asbestos by contractor); *Russell* v. *United States*, 763 F.2d 786 (10th Cir. 1985) (alleged negligence by MSHA in inspecting coal mine); *Hylin* v. *United States*, 755 F.2d 551 (7th Cir. 1985) (mine inspectors' alleged failure fully to inspect clay mine); *Feyers* v. *United States*, 749 F.2d 1222 (6th Cir. 1984) (Army's allegedly negligent failure to inspect contractor's operation of government-owned railyard), cert. denied, 471 U.S. 1125 (1985); *General Public Utilities Corp.* v. *United States*, 745 F.2d 239 (3d Cir. 1984) (NRC's alleged failure to warn of possible equipment defects at Three Mile Island nuclear facility), cert. denied, 469 U.S. 1228 (1985); *Natural Gas Pipeline Co.* v. *United States*, 742 F.2d 502 (9th Cir. 1984) (alleged negligence in FAA inspection and issuance of certificates for aircraft).

ment for negligence in conducting safety compliance checks. See *Collins* v. *United States*, 783 F.2d 1225 (5th Cir. 1986) (decision by Mine Safety and Health Administration to rescind an "Imminent Danger Order" and not to reclassify mine as "gassy" after inspection revealed high methane levels); *National Carriers, Inc.* v. *United States*, 755 F.2d 675 (8th Cir. 1985) (failure of meat inspector to require condemnation, tagging and separation of contaminated beef); *McMichael* v. *United States*, 751 F.2d 303 (8th Cir. 1985) (failure of Defense Department inspectors to enforce safety requirements on defense contractor). These courts distinguished *Varig Airlines* because the inspectors in question had no discretion not "to enforce the detected violations of the safety requirements" (*McMichael*, 751 F.2d at 307; see *Collins*, 783 F.2d at 1230-1231).

Petitioners argue (Br. 9, 13-14), in reliance on such cases, that when licensing and inspection activities are governed by mandatory regulations and an agency violates its own regulations in issuing a license or conducting an inspection, then the discretionary function exception does not apply. A regulatory agency is therefore liable as an insurer, petitioners assert, for the harm caused by any product granted a license or any hazard not detected in an inspection because of a failure to follow such "mandatory regulations."

That specific issue was not directly addressed in *Varig Airlines*. But the answer is nonetheless clear. The wording of the regulations does not change their essential nature, which is to promote safety by policing compliance. The operational burden (and, hence, the burden of negligence) remains with private industry. Allegations that the policeman has failed to do his job, however specifically defined, do not change his essential role from that of regulator to that of insurer.[19]

[19] *Hatahley* v. *United States*, 351 U.S. 173 (1956), upon which petitioners rely (Br. 12-13), is not on point. In that case, federal

More specifically, there are three related flaws with petitioners' argument. First, it ignores the wording of the discretionary function exception, which precludes liability whether or not the government has acted negligently by breaching one of its own regulations. Second, it largely eliminates the protection of regulatory functions—thereby frustrating the prime motivation for the discretionary function exception—because tort claims can almost always be couched in terms of mandatory duties left unperformed. Third, contrary to Congress's express intention, it interjects tort considerations into a regulatory agency's fundamental policy decision on how specifically to write its regulations (and, hence, how carefully to regulate private industry) by providing agencies with a strong incentive to avoid clear directives for enforcement personnel.

(i) The applicability of the discretionary function exception is determined by whether the agency *function* in

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agents, "with complete disregard for the property rights" of certain Navajo Indians (351 U.S. at 181), "vigorously prosecuted a campaign to round up and destroy [the Indians'] horses" in an effort to drive them from public land (*id.* at 176). The Court held that these tortious acts by the officials, committed within the scope of their employment, gave rise to an FTCA claim against the United States. The Court further held that these torts could not be excused post hoc by reference to federal regulations governing impoundment of lifestock unlawfully grazing on federal land because the notice procedures provided in those regulations were not observed (*id.* at 180).

The Court in *Hatahley* did not find that actionable torts had been committed *because* federal officials violated federal regulations. Rather, the Court held simply that the otherwise actionable torts of the officials were not excused by the regulations because, as the government conceded, there was no "attempt at any time to comply with" the regulations. 351 U.S. at 180. The government officials in *Hatahley* were not acting as regulators of private conduct, but rather as trespassers, and the Court thus said that no issue concerning the discretionary function exception was presented (*id.* at 181).

question is discretionary. If it is, then the function is protected regardless of allegations of negligence or other wrongful acts. Section 2680(a) contains two separate provisions, presented in the disjunctive. The first half of Section 2680(a) precludes liability for any "act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation * * *." No similar requirement—of due care in the execution of a statute or regulation—limits the second provision, the discretionary function exception.

The crucial inquiry in any case under the discretionary function exception, therefore, is not whether an agency inspector acted wrongly or negligently. Were that the test, the discretionary function exception would provide little protection, since it is usually the case that individual employees lack discretion to perform negligently or violate agency regulations. But what is at issue is the fundamental character of the function being performed. Licensing, certification and inspection are paradigms of discretionary functions as Congress understood that term. It follows that no liability may attach to those functions despite claims that the employees carrying them out disobeyed agency regulations or were otherwise negligent.[20]

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[20] Congress of course stressed that "the common-law torts of employees of regulatory agencies would be included within the scope of the bill to the same extent as torts of nonregulatory agencies." H.R. Rep. 2245, 77th Cong., 2d Sess. 10 (1942). Thus, the negligent driving of a mine inspector who gets in a car accident on his way to inspect a mine will give rise to liability. But there is an obvious and fundamental difference between driving a car to the site of an inspection and the quintessentially regulatory function of performing the inspection. That latter function is protected by the discretionary function exception whether or not negligently performed, and whether or not the alleged negligence is demonstrated by reference to a violation of agency regulations.

Petitioners here do not argue that the licensing of the Sabin vaccine was negligent in the sense that its benefits do not outweigh its costs.[21] Rather, they are arguing that DBS (the predecessor of FDA's Bureau of Biologics) was negligent per se because DBS failed, in violation of its own regulations, to require submission by the manufacturer of certain qualifying test results prior to licensing the vaccine. If DBS violated its own regulations, then DBS may well have acted wrongly or negligently. But the discretionary function exception shields from liability "both negligence and wrongful acts in the exercise of the discretion." *Dalehite*, 346 U.S. at 33.

(ii) To permit FTCA suits to be brought against regulatory agencies for their licensing, certification and inspection activities whenever it is alleged that a particular licensing or certification decision was reached or a particular inspection conducted in violation of agency regulations would transform the discretionary function exception from a bar to suit into a rule of pleading. Plaintiffs would merely be required to couch their pleadings in terms not of negligence—which is protected by the exception—but in terms of a violation of the regulations governing some employee's actions.

In most cases, it will be possible to break a particular regulatory action down into component parts and identify some element that arguably violates an applicable regulatory requirement. Litigation of the merits of such an assertion—concluding in a finding of liability if the assertion is borne out—would completely defeat the purpose of the discretionary function exception, which was to bar from the outset such challenges to the performance of discretionary governmental functions through the medium of an action in tort. Other remedies exist

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[21] That would be a foolish argument indeed in light of the fact that the Sabin vaccine has all but eliminated polio in the United States.

for a government agency's alleged breach of its statutory and regulatory obligations.[22] "The purpose of the FTCA is to provide individuals with a means of obtaining tort damages from the United States for injuries negligently inflicted by U.S. employees or agents, and it should not be used to solve the entirely separate, modern problem of alleged bureaucratic inaction and ineptitude." *Baxley* v. *United States*, 767 F.2d 1095, 1098 (4th Cir. 1985).

(iii) The injection of a tort remedy as a means of challenging regulatory action would create incentives that are particularly disruptive of certain sorts of regulatory activity. It would motivate agencies to avoid as much as possible regulations imposing mandatory duties on their own employees because such duties might serve as the basis for government tort liability. In many instances, this may greatly impair the effectiveness of the regulatory program.

In view of local pressures to keep mines open, for example, effective protection of the nation's miners may warrant mandatory regulations that direct subordinates to shut down mines or issue citations in certain specifically-defined circumstances. See *Collins* v. *United States*, *supra*. But if the discretionary function exception does not include all such activity within its ambit, regulators will have a significant disincentive to adopt such regulations. And this disincentive will be strongest in areas where such regulation is needed the most, areas in which the danger (and, hence, the potential liability) is greatest.

If licensing, certifications, and inspections are not completely covered by the discretionary function exception, those administering regulatory programs will be faced with the unpalatable choice of avoiding mandatory regulations, and thus rendering their programs less effective,

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[21] The APA, 5 U.S.C. (& Supp. IV) 551 *et seq.*, offers a comprehensive scheme for review of regulatory action.

or accepting the consequences in increased tort liability. Yet the discretionary function exception was specifically designed to permit a regulatory agency to fulfill its mission in the most effective manner without subjecting the United States to tort liability. Whether regulations should be written tightly or loosely, and how an agency may best ensure performance by its own employees and by the industry it regulates, are policy questions that the agency should be able to resolve without fear of damaging tort liability. See *Varig Airlines*, 467 U.S. at 819-820. If the Court's reading of Section 2680(a) causes agency heads to propose regulations that eschew direct governmental testing when such testing would be in the national interest, then the exception is clearly not working as intended.

In sum, we submit that Congress did not intend to expose the United States to monetary liability—essentially as an insurer—in connection with its role in licensing and inspecting private parties who fail to comply with mandatory health and safety requirements. Congress knows how to make the United States an insurer of a regulated industry when it wants to. See Section C, *infra* (discussing the National Vaccine Compensation Act). When it has not done so expressly, an agency cannot turn itself into an insurer of the industry it regulates simply by the wording of its regulations.

B. The FDA Licensing Process Is Indistinguishable From The FAA Certification Process For Purposes Of The Discretionary Function Exception

Even if the Court were to conclude that an agency's alleged violation of its own regulations governing licenses and inspections could give rise to a cause of action under the FTCA, the judgment below should still be affirmed. No violation of the regulations can be made out on the facts alleged by petitioners because the regulations at issue here do not impose mandatory duties on

the FDA.[23] FDA regulations governing the licensing of vaccines, like FAA regulations governing the certification of aircraft, place the primary burden of compliance on the manufacturer. The method, mode and extent of compliance review is left by the regulations to the discretion of FDA. This is true both for the product license issued to Lederle and for the release of the vaccine lot from which petitioner received his dose.

1. *The Product License*

Two sets of regulations govern the licensing of a poliovirus vaccine. First, there are generic regulations applicable to all product licenses (42 C.F.R. 73.1-73.83 (1963); 21 C.F.R. 600.3-601.26, 610.1-610.65).[24] Second, there are specific regulations that set the standards any live, oral poliovirus vaccine must meet (42 C.F.R. 73.110-73.118; 21 C.F.R. 630.10-630.17). The generic regulations provide that "[a] product license shall be issued only upon examination of the product and upon a determination that the product complies with the stand-

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[23] This case was disposed of on the government's motion to dismiss in lieu of an answer. Accordingly, the factual allegations in petitioners' complaint, though they would be hotly contested were the suit to go further, must be taken as true for purposes of this motion. What is certainly not assumed, however—even for purposes of the present litigation—is that the facts as alleged make out a violation of any mandatory regulations governing the FDA. That is a legal question that turns on the proper interpretation of those regulations. See *Varig Airlines*, 467 U.S. at 816-821. Indeed, it is the question decided by the court below. Petitioners are simply wrong in stating, however insistently (Br. 2, 8, 16, 20, 21, 22), that it is "admitted" that FDA violated its regulations.

[24] The first citation is to the regulations in effect at the time DBS licensed Lederle to produce the vaccine. Where the regulations have remained substantially in the same form, a parallel cite is given to the current regulations.

ards prescribed in the regulations" (42 C.F.R. 73.5(a); 21 C.F.R. 601.4(a)).[25]

Petitioners contend (Br. 16) that this provision imposes a mandatory duty that gives "agency employees no authority to exercise policy judgment in determining whether the conditions of licensing were met." However, this regulation does not, any more than the general statute (see 12-14, *supra*), specify either the nature of the "examination" to be conducted by DBS or the procedures to be used by DBS in making a "determination" that the product complies with the regulatory standards.

The regulations do not place any burden on DBS to conduct tests on the proposed product. To the contrary, the burden is squarely on the manufacturer to "submit data derived from laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity and potency" (42 C.F.R. 73.3; 21 C.F.R. 601.2(a)).[26] What DBS then does with that data—whether it duplicates certain tests, or painstakingly reviews the data for compliance, or simply spotchecks the application—is left to the agency's discretion. The regulations do specifically provide that the Surgeon General, when he deems it advisable "in matters involving the safety, purity and potency of • • • products for which an application for license is

[25] In addition to the product license, manufacturers must also obtain an establishment license (42 C.F.R. 73.2-73.4; 21 C.F.R. 601.1-601.2, 601.10) after passing an inspection demonstrating that the establishment complies with applicable standards relating to personnel, equipment, sterilization, care of lab animals, record keeping and other matters (see 42 C.F.R. 73.35-73.38). No challenge has been made here to the issuance of an establishment license to Lederle.

[26] The manufacturer is also required to designate a "responsible head who shall exercise control of the establishment in all matters relating to compliance with the provisions of this part" (42 C.F.R. 73.35(a); 21 C.F.R. 600.10(a)).

pending," may appoint a special board of three officers to review the "reports of inspection and laboratory examinations, together with any pertinent data the establishment may submit" (42 C.F.R. 73.12). The open-ended review process, of which this procedure is a part, clearly calls for considerable judgment on the part of the agency both in setting the standards and in policing compliance.[27]

Petitioners must therefore look to the specific regulations governing the oral polio vaccine to make their case that DBS violated mandatory regulations in granting Lederle a product license. Accordingly, petitioners allege (Br. 4-5), first, that DBS licensed the poliovirus strain used by Lederle even though "the strain violated the conditions for licensing prescribed in the regulations." Second, petitioners contend (Br. 5-6) that DBS licensed the particular "seed virus" used by Lederle to produce its vaccine without requiring Lederle to show that the "seed

[27] The decision to license a drug involves a determination, based on limited data, that its known benefits outweigh its potential risks. Thus, our level of uncertainty about a drug's unknown or unknowable risks is deemed acceptable at some point and the decision is made to license a drug with specific warnings. FDA Drug approval procedures have long been scrutinized by Congress, and have been found to reflect the highest standards for effectiveness and safety in the world.

Walsh & Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 Food Drug Cosm. L.J. 171, 178 (1986). In its list of approved licenses, FDA itself makes clear that "[t]he licenses granted to these establishments for the products listed in this publication do not imply an endorsement of the respective preparations nor do they make the Government a guarantor or insurer of the safety, purity, and potency of such licensed products." FDA, HHS, *Pub. No. 87-9003, Establishments and Products Licensed under Section 351 of the Public Health Service Act* ii (Apr. 1987).

virus" had been subjected to all required testing and complied with all regulatory standards.

Petitioners are confused on both counts. Contrary to their assertions (Br. 4-5), a license is not issued for the original poliovirus strain itself. Nor are seed viruses individually licensed. Rather, a product license is issued to a manufacturer to produce a vaccine using a particular poliovirus strain that has been found to meet the criteria for acceptable strains set out in 42 C.F.R. 73.110 (b)(2) (21 C.F.R. 630.10(b)(2)). The poliovirus strain at issue here, and the only live poliovirus strain found acceptable for use in the United States, is the strain developed by Dr. Sabin. The Sabin strain is not produced by the manufacturer. Rather, it is obtained directly from Dr. Sabin.

Once the manufacturer obtains the original virus strain from Dr. Sabin, it grows a seed virus from that strain. The seed virus is in turn used to produce the monopools from which portions are combined to make up the actual vaccine ingested by the public. But the seed virus is not separately licensed. Rather, manufacturers are simply forbidden by the regulations to use any seed virus without first performing certain prescribed tests to ensure that the neurovirulence of the seed virus "is no greater than that of the * * * Reference Attenuated Poliovirus" distributed by the agency. 42 C.F.R. 73.110 (b)(4); 21 C.F.R. 630.10(b)(4).

Accordingly, petitioners' claims must be slightly recast. They apparently intend to argue that DBS should not have granted Lederle a product license for Orimune because, first (Br. 4), the original Sabin strain never met the criteria for acceptable strains set out in 42 C.F.R. 73.110(b)(2), and, second (Br. 5), a seed virus to be used by Lederle—production seed 45-B-85—"had not been subjected to the neurovirulence testing required by" 42 C.F.R. 73.110(b)(4). Neither allegation, however, supports petitioners' contention that DBS violated a nondiscretionary regulatory requirement.[28]

The Sabin Strain. 42 C.F.R. 73.110(b) establishes "[c]riteria for acceptable strains" of attenuated poliovirus. It provides, inter alia, that "[p]oliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless * * * data are submitted to the Surgeon General which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least 100,000 people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained" (42 C.F.R. 73.110(b)(2)).[29] Petitioners allege (Br. 4) that DBS violated this regulation because "[t]he application submitted to DBS demonstrated that the virus strain for which a license was sought *caused* paralysis in the human test population and was not, therefore, 'without harmful effect.'"

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[28] Petitioners also allege (Br. 19) that "[a]fter production seed 45-B-85 was licensed, it demonstrated a change in neurovirulence, triggering the requirement that its license be revoked." As already noted (see note 7, *supra*), this claim is not properly presented. Moreover, the allegation makes no sense since petitioners are wrong in asserting (Br. 5) that "[e]ach production seed must be individually licensed." But those problems aside, it is clear from the regulations that the Surgeon General need only "recommend" revocation of a product license if "he finds, after notice and opportunity for hearing, that * * * the product for which the license has been issued, fails to conform to the standards in the regulations * * *" (42 C.F.R. 73.9; 21 C.F.R. 601.5). The Surgeon General's decision whether or not to institute such revocation proceedings is a classic exercise of enforcement discretion. *Heckler* v. *Chaney*, 470 U.S. 821 (1985).

[29] The current regulation (21 C.F.R. 630.10(b)(2)) differs from that in effect at the time of the events in issue only in the identity of the official to whom such data must be submitted (the Director, Office of Biologics Research and Review) and the number of persons tested (one million).

Even assuming, *arguendo*, that this regulation constitutes a mandatory direction to the Surgeon General not to grant a license without first receiving data qualifying the strain (rather than, as the words expressly state, a direction to the manufacturer not to "use[]" a strain for which such data have not been "submitted"), there is a major flaw in petitioners' argument. The Sabin strain was found acceptable for use in the United States based on data reviewed by a specially appointed committee of scientists eight months before the regulation in question (which was designed to state the requirements any *new* strain would have to meet) was promulgated and almost three years before Lederle was licensed to produce a vaccine using that strain. See *Polio Vaccines: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 87th Cong., 1st Sess. 346 (1961) [hereinafter *Hearings*] (statement of Surgeon General Burney). Under these circumstances, new data on the Sabin strain clearly were not required by the regulations.

In June 1958, Surgeon General Burney appointed a committee of six experts to examine the data available from field and laboratory studies on live poliovirus vaccine, recommend an acceptable strain for use in such a vaccine, and propose licensing requirements. See *Hearings* 328 (first report of the Public Health Service Ad Hoc Committee on Live Poliovirus Vaccine). At that time, three different strains of live virus had been developed and were being tested in vaccines throughout the world: the Sabin strain, the Cox strain and the Koprowski strain. Based on field experience with all the candidate strains, on August 19, 1960, the Committee recommended that the Sabin Strain, Types I, II and III (corresponding to the three types of the polio virus) be selected for use in the United States. In world-wide tests

over 100 million people had received vaccines produced from the Sabin strain without significant adverse effects. See *id.* at 36 (statement of Dr. Murray); *id.* at 332 (second report of the Public Health Service Ad Hoc Committee on Live Poliovirus Vaccine) ("No evidence had been reported to indicate that any of these vaccines produced any harm to these individuals to whom they were administered").[30] Accordingly, on August 24, 1960, Surgeon General Burney announced that the Sabin strain had been found "suitable for use in the United States." *Id.* at 346 (statement of Surgeon General Burney).

Dr. Roderick Murray, the Director of DBS, was a member of the Committee. The Committee worked closely with DBS in drafting regulations to govern the licensing of the live poliovirus vaccine. Although the Sabin strain alone had been found acceptable among the three candidates then known, DBS did not foreclose, and indeed encouraged, the possibility that a fourth strain would be developed. *Hearings* 347 (statement of Surgeon General Burney). Accordingly, instead of writing regulations that simply approved the Sabin strain for use in vaccines, the Committee drafted generic requirements that any new candidate would have to meet. These requirements were specifically written to reflect the criteria by which the Sabin strain had been evaluated, and which the Committee determined had been met by that strain. See *Hearings* 333 (second Committee Report recommending approval of Sabin strain contains same proposal as finally adopted for judging future strains based on "[f]reedom from harmful effects").[31] Petition-

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[30] The vaccine was also tested without harmful effect on 181,000 persons in Cincinnati in a program directed by Dr. Sabin starting in April 1960. *Hearings* 188, 226 (statement of Dr. Sabin).

[31] On November 23, 1960, a Notice of Proposed Rulemaking was published in the Federal Register. 25 Fed. Reg. 11111-11114. On March 25, 1961, the final regulations were published and became

ers' contention that the Sabin vaccine itself does not meet the criteria drafted with it in mind is thus wholly untenable.[32]

Furthermore, even if the regulations had not been written by a committee of experts to match the data already on hand concerning the Sabin strain, the phrase "without harmful effect" is clearly a wide-open term requiring considerable scientific and policy judgment as to what constitutes an acceptable risk under the circumstances. Petitioners' contention that the Sabin strain is unsafe is an attack on the most fundamental scientific/policy decision made by the Surgeon General on advice of the Committee. In effect, petitioners want a chance to enter the Salk/Sabin debate on the side of Salk and to hold the government liable for coming out the other way. That is precisely the sort of "judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort" that Congress was at pains to prevent. *Varig Airlines*, 467 U.S. at 814.

Seed Virus 45-B-85. Petitioners allege (Br. 5) that DBS should not have issued Lederle a product license for Orimune because a seed virus used by Lederle—production seed 45-B-85—was never "subjected to the neurovirulence testing required by the regulations."[33] Petitioners,

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effective on April 24, 1961. 26 Fed. Reg. 2564-2568. On August 17, 1961, the government issued the first license to manufacture the Sabin live polio vaccine, Type 1, to Pfizer Limited. On June 25, 1963, the government licensed Lederle to manufacture a trivalent live oral polio vaccine using the Sabin strain, Types I, II, and III.

[32] The Sabin strain was used as a "reference strain" by DBS, and is still so used by FDA. Manufacturers are required to obtain the strain from FDA for use as a control in performing required tests. 42 C.F.R. 73.111; 21 C.F.R. 630.14.

[33] In fact, Lederle did not begin using production seed 45-B-85 until 1966, three years after Orimune was licensed. Although Lederle did not have to obtain a new license in order to change its manufacturing process, it did have to perform certain prescribed

however, have ignored the language of the regulations, which do not place any burden on DBS employees to conduct tests themselves on the seed viruses used in the manufacture of the vaccine or to obtain such results from the manufacturer prior either to licensing the product or to approving the use of a particular seed virus. Rather, the poliovirus regulations (like the generic regulations discussed at 29-31, *supra*) are aimed directly at the manufacturer. They state that "[n]o seed virus shall be *used* for the manufacture of poliovirus vaccine unless its neurovirulence in Macaca monkeys is no greater than that of the NIH Reference Attenuated Poliovirus." 42 C.F.R. 73.110(b)(4) (emphasis added); 21 C.F.R. 630.10(b)(4). The regulations further specify in detail the "tests to be performed by the manufacturer" to demonstrate "the neurovirulence of the seed virus" (*ibid.*). "Subsequent and identical neurovirulence tests" must be performed by the manufacturers "upon introduction of a new production seed lot and as often as necessary otherwise to establish to the satisfaction of the Surgeon General that the seed virus strains for vaccine manufacture have maintained their neurovirulence properties" (42 C.F.R. 73.110(b)(5); 21 C.F.R. 630.10(b)(5)). The regulations nowhere purport to limit the discretion of, or impose mandatory duties on, the Surgeon General by specifying what he must do before he can be "satisf[ied]" that a particular seed virus meets the requirements.

As the court of appeals here stated (Pet. App. 18a n.6), in taking issue with the Ninth Circuit's decision in *Baker* v. *United States*, 817 F.2d 560 (1987),[34] "[w]e do

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tests and obtain DBS's approval to begin using the new seed virus. We will assume, therefore, that it is DBS's approval of the seed virus that petitioners are attacking.

[34] In *Baker*, the plaintiff alleged that DBS violated its own regulations when it failed to require submission of test data before making

not agree * * * that the FDA is under a duty to require submission of test data. Rather, the duty to submit test data rests with the manufacturer." The Ninth Circuit inferred from the detail of FDA's safety requirements that the agency had exercised its administrative discretion in favor of exhaustive inspection designed to guarantee the safety of vaccines. But the purpose of the detailed standards is to guide *manufacturers* in producing safe vaccines; the standards do not lessen the FDA's inherent discretion to decide how to allocate its resources in attempting to enforce the regulations or shift the burden to the FDA to guarantee compliance. Accordingly, an alleged failure by the agency to ensure that the manufacturer submitted test results, as required by the regulations, cannot form the basis for an FTCA suit.[35] "When an agency determines the extent to which it will supervise the safety procedures of private individuals, it is exercising discretionary regulatory authority of the most basic kind" (*Varig Airlines*, 467 U.S. at 819-820).

2. *The Lot Release*

Petitioners' final allegation (Br. 6-7, 20-21) is that the FDA wrongfully released the specific lot of vaccine from which Kevan Berkovitz received his dose on May

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its licensing decision. The Ninth Circuit concluded that the agency "may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted," and that the agency thus has a mandatory duty to require the submission of that data (*id.* at 566). The court was unwilling to apply the discretionary function exception to the plaintiff's allegations of "a negligent failure to obey a mandatory regulatory command" (*ibid.*).

[35] Failure to obtain such data from a manufacturer prior to approval might indicate negligence on the part of the agency, but of course the discretionary function exception shields from liability "both negligence and wrongful acts in the exercise of the discretion" granted to the agency. *Dalehite*, 346 U.S. at 33.

10, 1979. Petitioners acknowledge (Br. 20-21) that the regulations place the burden directly on the manufacturer "to test each vaccine lot for compliance with prescribed neurovirulence criteria and to submit the test results to the agency." They note, however (Br. 21), that the FDA is "empowered" to prevent distribution of a noncomplying lot. Petitioners contend (Br. 7) that the data submitted by the manufacturer concerning the particular vaccine lot in question here revealed excessive neurovirulence and that independent agency tests "confirmed that the vaccine exceeded the regulatory standards."[36] Under these circumstances, petitioners argue,

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[36] A trivalent vaccine such as Orimune is made from portions of monopools of each of the three types of poliovirus, and neurovirulence tests are performed on the individual monopools, not on the vaccine itself, 21 C.F.R. 630.17(b). We assume, therefore, that what petitioners intend to allege is that one of the monopools exceeded the permissible level of neurovirulence.

A related misstatement by petitioners is more significant. On page ten of their statutory appendix, petitioners purport to quote portions of 21 C.F.R. 610.2, concerning "requests for samples and protocols" and release "of any lot of any licensed product." Section 610.2(a), in fact and as quoted, states that the Director of the Bureau of Biologics "may" require submission of test results on a lot and further may, "when deemed necessary for the safety, purity, or potency of the product," notify the manufacturer "not [to] distribute a lot of a product until the lot is released by the Director." 21 C.F.R. 610.2(a) (1978) (the current regulation is identical except for the identity of the agency official). Clearly, this language embodies no mandatory guideline limiting the Director's discretion in deciding either to examine test results or to release a given lot.

Petitioners proceed, however, to set forth language which they refer to as Section 610.2(b), which is in fact drawn from 21 C.F.R. 630.17(b). In its proper context, that language is plainly directed at the manufacturer, indicating tests to be performed by the manufacturer, not by the agency. The mis-labelling of this section places it in a context where it might be misunderstood to impose an obligation on the agency.

the agency had a mandatory duty not to release the noncomplying lot.

As the court of appeals correctly noted (Pet. App. 20a-21a), petitioners are simply arguing that release of the lot, under these circumstances, was negligent or otherwise wrongful. The discretionary function exception, however, shields from liability "both negligence and wrongful acts in the exercise of the discretion." *Dalehite*, 346 U.S. at 33. The crucial point is that the FDA is exercising discretion when it decides to examine test results or to conduct its own tests. Failure to block release of a noncomplying product following such an examination may be an abuse of that discretion—see *ibid.* 346 U.S. at 33 ("The exercise of discretion could not be abused without negligence or a wrongful act")—but Section 2680(a) precludes suit "whether or not the discretion involved be abused."

The FDA should not be held to a higher standard—as a guarantor of compliance—because it elected to do more than "spot-check" compliance. An alternative holding, as the court of appeals noted (Pet. App. 21a), "would inhibit the agency's selection of the mechanism for compliance review" and "[t]his is precisely what *Varig* instructs us not to do." The court of appeals therefore correctly concluded (*ibid.*) "that when the FDA makes the discretionary choice to examine or test samples which it has discretion not to test, it cannot be held liable for subsequent negligence at the operational level in implementing its decision to test." The ultimate responsibility for ensuring that a vaccine complies with regulatory requirements rests with the manufacturer,[37] and FDA does not relieve the manufacturer of, or itself assume, that responsibility however "methodically [FDA] examine[s] test results or test[s] vaccine samples" (Pet. App. 21a).

[37] As already noted note 6, *supra*, petitioners in fact obtained a settlement from Lederle.

C. The National Childhood Vaccine Injury Act Confirms That Congress Did Not Intend For The FDA To Be Held Liable Under the FTCA For Injuries Caused By Vaccines

Nothing in the Public Health Service Act remotely shows a Congressional intent to make the FDA an insurer of vaccines and other drugs, and the FDA has not been delegated any authority to turn itself into such an insurer by the wording of its regulations. Congress knows how to set up an insurance program for a regulated industry when it wants to, and when it does so the program looks very different from an ordinary regulatory scheme. We know that, because in 1986 Congress passed just such a program in the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755.[38]

The Act establishes a National Vaccine Injury Compensation Program applicable to all claims in excess of $1,000 against a vaccine manufacturer or health service provider that administers a vaccine, based on vaccine-related injuries. §§ 2110-2111. Claimants must file an affidavit in Claims Court setting forth the nature of

[38] The 1986 Act had no effective date; rather it was not to become effective until funded. Congress subsequently passed the Vaccine Compensation Amendments of 1987 as part of the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330. These amendments made the effective date of the program October 1, 1988. Congress authorized (though it has not yet appropriated) $80 million for each year through 1992 to pay for claims arising before the effective date of the Act. Cases arising after the effective date are to be paid from a Trust Fund funded by an excise tax on certain vaccines. See § 2115(i)-(j) (all citations are to the Act as amended in 1987). The Trust Fund is also subrogated to the rights of claimants up to the amount of compensation paid, so that the Fund can seek reimbursement for negligence by vaccine manufacturers. § 2117. By way of fiscal control, the Act contains strict limitations on the numbers of claims that may be filed in each category, and the program automatically terminates if those numbers are exceeded. § 2184.

their injuries, the date, place and nature of the vaccine taken, and assurances that they have not previously collected any award or settlement of a damage action for the injuries in question. § 2111(c). Hearings are held by a Special Master on the issues of causation and damages, with de novo review by the court. No showing of fault or negligence is required. § 2112. Compensation includes actual and projected unreimbursable expenses that resulted from the vaccine-related injury, such as reasonably necessary medical, remedial, and rehabilitative care, including special education, vocational training, emotional or behavioral therapy, special equipment, and residential and custodial care ($250,000 is awarded for any vaccine-related death). § 2115(a). Actual and projected pain and suffering and emotional distress are also reimbursable in an amount not to exceed $250,000. *Ibid.* The Act also provides for reasonable attorneys' fees. § 2115(e). No punitive damages are permitted. § 2115(d). Those with pending civil actions against a manufacturer or administrator of the vaccine may withdraw them without prejudice and elect to file a petition. § 2111(a)(5)(A). Those, however, who have already received damages awarded either under a judgment of a court or a settlement of such action may not file a petition. § 2111(a)(7).[39]

Once a compensation award is fixed, the claimant may elect either to accept the award or to file a civil action against the manufacturer. § 2121. The Act, however, makes certain changes in state tort law that make such an action more difficult.[40] Thus, the claimant would have

[39] Thus, Kevan Berkovitz is not eligible for the program at all in light of his settlement with Lederle.

[40] For example, a manufacturer cannot be held liable for unavoidable injuries caused by a vaccine that was properly prepared and was accompanied by proper directions and warnings. A vaccine is presumed to have been properly prepared if the manufacturer complied with all FDA requirements. § 2122.

to forego a guaranteed compensation package from the program in order to pursue a more uncertain remedy against the manufacturer of the vaccine. The Act was spurred by a perceived need not only to compensate the rare victims of a program that provides overwhelming benefits to the population generally, but also to protect manufacturers of vaccines from ruinous damage awards so as to ensure the continued availability of those vaccines. Congress wanted to substitute a national insurance program for the vagaries of the tort system in this essential area.[41]

Congress thus provided claimants with a remedy against the United States as a substitute for a tort action against the manufacturer or the provider that administers the vaccine. A crucial premise of this program is that persons injured by vaccines do not already have a tort remedy against the United States for having licensed the vaccine. "Currently," Congress noted (H.R. Rep. 99-908, *supra*, at 6), "vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with

[41] H.R. Rep. 99-908, 99th Cong., 2d Sess. Pt. 1, at 4-5 (1986) (program necessary because the great success of vaccines is being threatened by mounting liability costs, which have caused prices to go up and the number of manufacturers to go down). See also Mann, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 Vand. L. Rev. 235 (1976) ("Drug manufacturers have ceased, or are threatening to cease, production of these essential, life-saving vaccines. Consequently, these recoveries threaten the effectiveness of the nation's preventative health care programs and contravene the strong public policy of combating infectious disease through widespread vaccination campaigns.").

The administration, it should be noted, does not believe that the Act as passed will in fact have these salutory effects. The Administration opposed the Act in its current form and offered its own alternative bill, H.R. 4777, that would have established a program for vaccine-related injuries along the lines of current workers' compensation programs.

the vaccine manufacturer." Accordingly, in order to make the program an exclusive remedy for vaccine-related injuries, Congress only barred tort suits against "manufacturers and administrators" of vaccines except pursuant to the terms of the Act. No similar bar was placed on FTCA suits against the United States, presumably because Congress viewed the discretionary function exception as a bar to such suits.[42] For the Court now to overlay this insurance scheme with tort liability under the FTCA would wholly disrupt the Act and undermine Congress's attempt to fund the program with a minimum drain on the public fisc. See note 38, *supra*.

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[42] Thus, in the National Swine Flu Immunization Program of 1976, 42 U.S.C. (1976 ed.) 247b(j)-(*l*), the government, in an earlier effort to provide necessary assurance to drug manufacturers by making lawsuits against the government the exclusive remedy for all actions connected with the Swine Flu Program, accepted all liability "for personal injury or death arising out of the administration of swine flu vaccine." In order to permit such suits, Congress expressly waived the discretionary function exception. 42 U.S.C. (1976 ed.) 247b(k)(2). Similarly, Congress has made the discretionary function exception inapplicable to any "grossly negligent" exercise or performance of a discretionary function by the Consumer Products Safety Commission. 15 U.S.C. 2053(h). Needless to say, waivers of this sort would be unnecessary if Congress thought the United States could be liable under the FTCA for its regulatory activity in licensing products.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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REPLY BRIEF FOR PETITIONERS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

ARGUMENT 1

I. The argument for per se immunity rests on the "governmental function" doctrine, which has been rejected by the Court in three prior cases. The argument is contradicted by legislative history expressly indicating Congress' intent not to except regulatory agencies from the waiver of immunity 1

II. The argument that it is the agency's "basic function", rather than particular acts of misconduct, which determines the applicability of section 2680(a) is no more than a restatement of the "governmental function" doctrine. The government's assertion that specific acts of negligence are not relevant is contradicted by the statute itself, by Dalehite and by Varig 3

III. That an agency has initial authority to promulgate regulations carrying into execution its statutory mandate does not render all subsequent conduct discretionary. This argument, if adopted, would create broad immunities for federal conduct, contrary to Congress' express intent in enacting the FTCA 5

IV. The government's argument that a finding of liability here would "eliminate" protection for regulatory functions and create unprecedented liability is baseless 8

V. The government's effort to bring this case within the shelter of Varig by generalizing about regulatory "process" is unavailing. There is no language in the statute or regulations here which confers either discretion not to examine the license appliance for demonstrated compliance or discretion to license despite noncompliance 11

TABLE OF CONTENTS—Continued

	Page
VI. Regarding the lot release approval, proof that the agency interpreted applicable regulations as mandatory in the circumstances presented here would entitle Petitioners to relief. The claim should not, therefore, be dismissed	15
VII. The government's attempt to put facts in dispute illustrates the inappropriateness of dismissal of the case under Rule 12. The extra-judicial facts asserted by the government, even if accepted, do not alter the core question presented	17
VIII. The National Childhood Vaccine Injury Act has no bearing on the issues presented here	18
CONCLUSION	20

TABLE OF AUTHORITIES

CASES:	Page
Brooks v. United States, 337 U.S. 49 (1949)	19
Conley v. Gibson, 355 U.S. 41 (1957)	17
Dalehite v. United States, 346 U.S. 15 (1953)	*passim*
Federal Election Committee v. Democratic Senatorial Campaign Committee, 454 U.S. 27 (1981)	16
Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972), *aff'd*, 500 F.2d 1059 (3d Cir. 1974)	3, 13, 16
Indian Towing v. United States, 350 U.S. 61 (1955)	2, 6
Owen v. City of Independence, 445 U.S. 622 (1980)	8
Rayonier v. United States, 352 U.S. 315 (1957)	2, 8
United States v. Muniz, 374 U.S. 150 (1963)	2, 11
United States v. S.A. Empresa Aerea De Viacao Rio Grandense (Varig Airlines), 467 U.S. 797 (1984)	*passim*

STATUTES AND REGULATIONS:	
National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755	5, 18
5 U.S.C. § 301	5
12 U.S.C. § 1817	10
28 U.S.C. § 1346(b)	4
28 U.S.C. § 2674	2
28 U.S.C. § 2680(a)	*passim*
42 U.S.C. § 247b(k)	19
42 U.S.C. § 262	10, 17
49 U.S.C. § 1421(a)	11
49 U.S.C. § 1421(c)	13
21 C.F.R. § 610.2	15, 16
21 C.F.R. § 630.17(b)	16
42 C.F.R. § 73.5	13
42 C.F.R. § 73.12	14
42 C.F.R. § 73.110(b)(5)	18
42 C.F.R. § 73.114	13
42 C.F.R. § 73.114(b)	13
42 C.F.R. § 73.115	13
42 C.F.R. § 73.117	13

TABLE OF AUTHORITIES—Continued

MISCELLANEOUS: Page

U.S. Const., Art. III, § 3 5

Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U.Chi.L.Rev. 1300 (Fall 1987) 7

REPLY BRIEF FOR PETITIONERS

ARGUMENT

The government's brief demonstrates that the only basis for immunizing the conduct challenged here would be creation of an exception providing per se immunity for regulatory conduct. Three arguments are advanced in support of creating a *per se* exception: (i) that regulatory conduct is a uniquely governmental function, entitled to *per se* immunity under the Tort Claims Act; (ii) that the Court must look not at the particular misconduct alleged, but rather at the "basic function" of the agency in determining whether immunity is preserved under section 2680(a); and (iii) that an agency's initial exercise of discretion in promulgating regulations must be found to immunize *all* subsequent conduct of the agency. It is clear from these arguments that the government's objective is to persuade the Court to import broad immunities back into a statute expressly designed by Congress to limit such immunities.

I. The argument for per se immunity rests on the "governmental function" doctrine, which has been rejected by the Court in three prior cases. The argument is contradicted by legislative history expressly indicating Congress' intent not to except regulatory agencies from the waiver of immunity.

As noted in Petitioner's opening brief, there is neither textual nor precedential support for the government's claim that section 2680(a) extends *per se* immunity to all regulatory conduct. (Pet. Br. 28-30). The government endeavors to recast the argument by asserting that regulatory activity is a "uniquely governmental function" having "no counterpart in the private sector" and on that basis enjoys *per se* immunity under the statute. (Br. 16, 19-21, 25.) [1] First, it should be noted that this argument

[1] The government also cites dicta from *Dalehite* referring to section 2680(a) as the "governmental regulatory function exception from suits". (Br. 17). However, that portion of *Dalehite* approving the governmental function test was subsequently over-

rests on section 2674 of the Tort Claims Act providing that the government shall be liable in the same manner and to the same extent as a private individual. (SA-1) The issue whether Petitioners have made out a *prima facie* case under the section has not been presented to the court.[2] Further, this Court has on three prior occasions rejected assertions that "governmental functions" enjoy *per se* immunity under the Tort Claims Act, holding that Congress did not create such as exemption and that, "There is no justification for this Court to read exemptions into the Act beyond those provided by Congress." *Rayonier v. United States*, 352 U.S. 315, 320 (1957). *See, also, Indian Towing v. United States*, 350 U.S. 61, 68 (1955); *United States v. Muniz*, 374 U.S. 150 (1963).

Petitioners' have cited legislative history plainly setting forth Congress' intent *to waive immunity for the tortious conduct of regulatory employees*, thus explicitly contradicting the government's assertion that Congress intended to preserve *per se* immunity for regulatory agencies.[3] The government responds by arguing that Congress contemplated only "ordinary tort liability", *i.e.*, negligent operation of motor vehicles, and that the government's exposure is fixed at this "traditional" concept of negligence. (Br. 15, 25, n.20). The government's posi-

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ruled. *Rayonier, Inc. v. United States*, 352 U.S. at 315. The government also argues that prior legislative proposals specifically excepting certain agencies demonstrate Congress' intent to protect all regulatory activities. (Br. 18). To the contrary, Congress' rejection of these proposals demonstrates its intent to preserve immunity only for a particular stratum of agency conduct—that implicating Executive decision-making prerogatives.

[2] *See, Brief for Petitioners*, 2, n.1, regarding the procedural history below.

[3] The exception is "designed to preclude application of the bill to a claim against a regulatory agency . . . based upon an alleged abuse of discretionary authority . . . However, the common-law torts of employees of regulatory agencies would be included within the scope of the bill to the same extent as torts of nonregulatory agencies." *Dalehite*, 346 U.S. at 29-30, n.21 (reviewing legislative history).

tion cannot be squared with the express terms of the Tort Claims Act, which provides in section 1346(b) that liability is to be determined "in accordance with the law of the place where the act or omission occurred." Congress purposefully adopted a standard of liability linked to the states' common law, which is an *evolving* standard of liability.[4] This Court has held that "the very purpose" of the Tort Claims Act was to waive governmental immunity from tort actions and *"to establish novel and unprecedented liability."* *Rayonier, supra*, 352 U.S. at 319 (emphasis added). There is no rational basis for a finding that Congress' express waiver of immunity for the tortious conduct of employees of regulatory agencies encompasses no more than the agency's truck driver.[5]

II. The argument that is the agency's "basic function", rather than particular acts of misconduct, which determines the applicability of section 2680(a) is no more than a restatement of the "governmental function" doctrine. The government's assertion that specific acts of negligence are not relevant is contradicted by the statute itself, by Dalehite and by Varig.

The government argues that the Court may not look beyond the basic function performed by the agency in determining whether a given case falls within the ambit of section 2680(a) immunity and that the particular conduct alleged to be wrongful is not relevant to the analysis. (Br. 10, 24-25). Emphasizing "function" as opposed

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[4] The evolving nature of Pennsylvania's common law is demonstrated by such cases as *Sinn v. Burd*, 486 Pa. 146, 404 A.2d 672, 679 (1979), observing that, "Every cause of action in tort . . . was once a novel claim" and holding that in ruling on preliminary objections for failure to state a cause of action, "the fact that the theory for recovery relied upon has not previously been sanctioned, is not conclusive."

[5] *Griffin v. United States*, 351 F.Supp. 10 (E.D. Pa. 1972), *aff'd*, 500 F.2d 1059 (1974), resulted in a $2,059,946.25 verdict against the government. If such a result were inconsistent with Congress' intent, amendment to clarify the Act's preservation of immunity for such codnuct would be expected.

to "act" is simply a semantic variation on the argument that governmental functions, including regulatory functions, are entitled to *per se* immunity under the Act. As the preceding section demonstrates, that theory is not tenable.

The government's argument is also at odds with the express language of the statute and with every decision of this Court construing the statute. Section 1346(b), for example, refers to liability in terms not of function, but of *acts or omissions*.[6] In *Dalehite* the basic *function* being performed by the War Department was patently discretionary.[7] That that was *not* a sufficient basis to support a finding of immunity is evident in the Court's extensive analysis of the specific *acts* of negligence alleged to have occurred in executing that function. The essential holding of the case is that, "*acts* of subordinates in carrying out the operations of government in accordance with official directions" are protected. *Dalehite*, *supra*, 346 U.S. at 33.[8] The same analysis of discrete conduct was undertaken in *Varig*, where the holding of the case also emphasized the focus on particular conduct; the question of immunity was found to turn on "whether the challenged *acts* of a Government employee . . . are of the nature and quality that Congress intended to shield from liability." *Varig*, *supra*, 104 S.Ct. at 2765 (emphasis added).

Thus the argument for protected "functions" is expressly contradicted by the statute, the legislative history, and the two major interpretative cases announced by this Court.

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[6] This section is set forth at SA-1.

[7] "That the cabinet-level decision to institute the fertilizer export program laws a discretionary act is not seriously disputed.' *Dalehite*, 346 U.S. at 37.

[8] The legislative history includes reference to protected "conduct" and "discretionary acts". *Dalehite*, 346 U.S. at 29-30, n. 21 (reviewing legislative history).

III. That an agency has initial authority to promulgate regulations carrying into execution its statutory mandate does not render all subsequent conduct discretionary. This argument, if adopted, would create broad immunities for federal conduct, contrary to Congress' express intent in enacting the FTCA.

A central theme running throughout the Government's Brief is that an agency's authority to formulate regulations governing its own conduct demonstrates its discretion; that *all* conduct which "flows from" that exercise of discretion is immune; and that if agencies are not immune for all executory conduct, including violation of mandatory regulations, agencies will have a disincentive to promulgate mandatory standards. (Br. 23, 27).

First, it should be noted that the government's position runs directly counter to the constitutional duty of the Executive to "take care that the Laws be faithfully executed." U.S. Const., Art. III, § 3. The regulations, once promulgated, have the force and effect of law and must be faithfully executed.

Further, *every* agency has authority to promulgate internal regulations.[9] Adoption of the government's position—that the initial exercise of discretion in promulgating regulations immunizes all subsequent conduct—would amount to judicial repeal of Congress' waiver of immunity in the Tort Claims Act. This view is also contradicted by the language of section 2680(a), which in the first clause preserves immunity for *non-negligent* conduct undertaken *in execution of a regulation* or statute. This clause would be meaningless if the fact that regulations were promulgated at all was sufficient to trigger blanket immunity for all executory conduct.

The government cites *Dalehite* in support of its assertion that all acts which "flow from" the initial exer-

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[9] In addition to specific grants of authority in enabling statutes, agencies have authority under 5 U.S.C. § 301 to "prescribe regulations for the government of the department . . . and performance of its business."

cise of discretion are immune. (Br. 17). The government would perpetuate the error of the panel majority below by omitting *Dalehite's* critical requirement that such conduct be *in accordance with official directions.* 346 U.S. at 36. The Court was explicit in its reason for extending immunity to such conduct. If obedient implementation of policy judgments were not covered, protection for the policy-maker would fail at the time it was most needed, i.e., when the policy was put into execution. To permit a challenge to obedient implementation of the policy would be to permit a back-door challenge to the policy itself. That rationale has no application to *disobedient* implementation of policy, and *Dalehite* does not authorize extending immunity to subordinate conduct which *violates* official directions.

Subsequently, in *Indian Towing*, 350 U.S. at 66, the Court specifically rejected the government's argument that all conduct related to the "end-objective" of a discretionary policy is protected, employing an extended hypothetical to illustrate how unworkable such a standard would be.

On a policy level, the government claims that if regulatory agencies are not protected from liability for violation even of mandatory regulations—protection which could only be achieved by a *per se* rule—agencies will have a disincentive to promulgate mandatory standards, and the public safety will thus be compromised. The government fails to explain, however, how public safety is *promoted* by allowing subordinate employees to ignore mandatory regulations designed to assure the safety of live-virus vaccines. The position advocated by the government would create a disincentive to be careful, which poses a far greater threat to effective federal regulation.

The position the government asks this Court to endorse assumes that the regulations will *not* be executed with due care. This assumption is not good policy. Congress' expectation, made explicit in the due care requirement of the first clause of section 2680(a), is directly to the

contrary. Congress obviously was not concerned that agencies would be inhibited by the imposition of liability for tortious *execution* of agency directives. If that were so, Congress would never have waived sovereign immunity. What motivated Congress was rather a separation of powers concern—to prevent the judiciary from second-guessing the reasonableness of the Executive's *policy judgment.* Separation of powers concerns are not implicated by judicial review of non-discretionary *execution* of policy judgments.

The argument that financial liability may create a disincentive to creation of stringent standards governing internal conduct may have force when applied to a private entity. However, federal agencies are created to serve a public, rather than profit-seeking purpose.[10] The government argues that regulatory agencies will be faced with "the unpalatable choice of avoiding mandatory regulations . . . or accepting the consequences in increased tort liability." (Br. 27-28). There is a third choice, the only responsible choice for administrators charged with public duties: promulgating whatever regulations are necessary to meet Congress' mandate to safeguard the public welfare and then making clear to subordinate employees that unless authority to exercise policy judgment

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[10] Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U.Chi.L.Rev. 1300, 1328-29:

> Most important, the government presumably is not as concerned with the 'bottom line' as private industry—the reason why it decides to regulate in the first place is to ensure a greater measure of safety for employees, passengers, and other third parties. The narrow argument that imposing tort liability will cause the government to abandon such activity or promulgate only general guidelines ignores the many social and political factors other than FTCA liability which impinge on the government's regulatory activities. Because a significant political constituency will favor regulatory action, any incentives agencies may have to avoid FTCA exposure, will simply result in a greater political 'push' by Congress, most likely in its authorization statutes, to bind agencies to a mandatory regulatory framework.

in implementing the regulations is expressly conferred, they must be obeyed.

Financial responsibility for the failure of agency employees to use due care in executing non-discretionary regulations does not devolve on the agency, but "is spread among all those who contribute to the support of the Government", since the public "as a whole benefits from the services performed by government employees." *Rayonier, supra*, 325 U.S. at 320. It is not tenable to suggest that regulators will opt to protect the public purse at the expense of the public health, particularly since risks to the public purse could be wholly avoided by faithful execution of the regulatory plan. Therefore, there exists no legitimate disincentive to adoption of whatever standards the agency deems necessary to fulfill its public function. Further, this Court has previously observed that, "as an empirical matter, it is questionable whether the hazard of municipal loss will deter a public officer from the conscientious exercise of his duties," *Owen v. City of Independence*, 445 U.S. 622, 656 (1980).

Finally, and perhaps most significantly, even should the Court be concerned that such a disincentive might exist, that is not a concern that can be accommodated within the terms of the Tort Claims Act. The only rule of immunity broad enough to satisfy this argument is a *per se* rule, which cannot be squared with the statute, its legislative history, or any case decided since the statute's enactment. Congress may choose to accommodate this concern by amending the Tort Claims Act. "If the Act is to be altered that is a function of the same body that adopted it." *Rayonier, supra*, 352 U.S. at 320.

IV. The government's argument that a finding of liability here would "eliminate" protection for regulatory functions and create unprecedented liability is baseless.

The government argues that a finding of liability here would: (i) eliminate protection for regulatory functions (Br. 24); (ii) subject the government to unprecedented liability for a broad range of inspection activities (Br. 20); and (iii) enable future litigants to avoid the discretionary function exception simply by *pleading* that a mandatory regulation has been violated (Br. 26). Such arguments are baseless. This case has inherent limiting principles, arising from the extraordinary stringency of the particular statute and regulations at issue, which would preclude its application in all but a narrow class of cases, if at all.

First, it is clear that the agency could avoid liability under the principles enunciated here simply by following its own regulations. It should not be regarded as extraordinary to expect an agency to abide by the law and by its own duly promulgated rules of conduct. Petitioners are not asking the agency to be an *insurer* of vaccine safety, as the government claims. If agency employees act in conformity with non-discretionary regulations and nonetheless fail to prevent harm, the agency would *not* be subject to liability. If the statute and regulations give agency employees discretion to exercise policy judgment in implementing the regulatory plan, the agency will not be liable for errors in judgment. Protection for regulatory functions is thus not "eliminated". To the contrary, *Varig* will remain the principal case defining the scope of immunity for regulatory conduct, since it is so much broader in application that the present case. The holding here will not alter *Varig* or diminish the scope of immunity presently provided by that case.

The government next argues that "the potential liability of the United States for failure to uncover defects or improprieties pursuant to regulatory inspections is staggering," (Br. 20) and cites some two dozen inspection schemes which it claims would subject the government to unprecedented liability if Petitioners' position is sustained. However, this is *not* an inspection case; employees here were not charged with the responsibility of "uncovering improprieties" at aircraft plants or meatpacking houses or banks. Their task was much more narrowly defined: review of a license application to determine whether compliance with specified regulations

was demonstrated on the face of the document presented to them. This is not a "policeman's" role. Rather, in section 262(d) of the Public Health Service Act Congress acted to lock laboratory doors of biologic products, authorizing their release through issuance of a license *only* upon a showing of regulatory compliance. Under this statute the agency is a jailer, authorized to unlock the doors *only* when regulatory compliance is demonstrated.

A finding that the government may be subjected to liability here would thus be based on the following specific factors: (i) enabling legislation which imposes non-waivable restrictions on agency power and does not give implementing employees discretion to create exceptions to licensing requirements; (ii) regulations which define compliance standards in objective terms and do not require—or permit—the exercise of policy judgment in determining whether such standards are met; (iii) regulations which identify precisely the scope of compliance review and leave no room for policy judgment in deciding what test results are relevant to the licensing decision; and (iv) violation of non-discretionary directives by an employee acting without authority to exercise policy judgment. None of the statutory schemes cited by the government in an attempt to hector the Court with forecasts of "staggering liability" meet these criteria. In none of the cited examples could the rationale of this case be applied to subject the government to liability for "failure to uncover defects or improprieties". To the contrary, such cases would continue to fall within the ambit of immunity set forth in *Varig*.

The government nonetheless argues that future litigants would be able to circumvent the exception simply by *pleading* that mandatory regulations were violated. (Br. 20). This argument is nonsense. Take, for example, a complaint which alleges violation of "mandatory" inspection requirements under 12 U.S.C. § 1817. (Br. 20). A federal judge would take one look at the statutory language—the agency "may, in its discretion" inspect records—and dismiss the case, likely imposing Rule 11

sanctions in the process.[11] The government's claims here are wholly without foundation.

V. The government's effort to bring this case within the shelter of Varig by generalizing about regulatory "process" is unavailing. There is no language in the statute or regulations here which confers either discretion not to examine the license appliance for demonstrated compliance or discretion to license despite non-compliance.

It is significant that the government's argument is again framed in terms of "process" and largely avoids specific reference to the statute and regulations which govern this agency's conduct. The thrust of the entire Brief is rather to obscure the specific mandates at issue here by generalizing about regulatory processes. The government asserts that, "The principal lesson in *Varig Airlines* is that federal regulatory agencies have 'a statutory duty to *promote* safety' in the industries they regulate, 'not to insure it'." (Br. 21-22). The actual quote, of course, reads: "The FAA has a statutory duty to *promote* safety in air transportation, not to insure it." *Varig Airlines*, 467 U.S. at 821 (emphasis in original). The Court was not theorizing about the generalized function of regulatory agencies. It was quoting from the enabling legislation of the FAA: "The Administrator is empowered and it shall be his duty to promote safety of civil aircraft in air commerce." 49 U.S.C. 1421(a). The government concedes that the issue presented here—failure to obey mandatory regulations—"was not directly addressed in *Varig*", but finds the answer to be "nonetheless clear. The wording of the regulations does not change their essential nature, which is to promote safety by policing compliance. (Br. 23).

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[11] "Federal rules of procedure are not so inflexible that clearly frivolous suits need embarrass (sic) prison officials or burden United States Attorneys' offices." *United States v. Muniz*, 374 U.S. 150, 164 (1961). *Muniz* indicates, however, that the government may be "subjected to the burden of pretrial preparation, discovery, and trial" to establish its defense on the merits. *Id.* at 162.

The government is wrong. The "essential nature" of the regulations at issue here is defined *not* by the enabling legislation of the FAA, but by the statute and regulations which empower *this* agency to act. And nowhere in the statute or regulations here does the word "promote" appear. The mandatory wording of these regulations is fully *consistent* with the "essential nature" of this statutory scheme, which is to insure that live-virus products which do not meet regulatory safety standards are not licensed.[12] The statutory mandate of the FAA is relevant only to demonstrate the profound *differences* in these two regulatory systems.

On a somewhat more specific level, the government argues that the process here is "indistinguishable" from the FAA process reviewed in *Varig* because: (i) like the FAA, the FDA has no duty to conduct tests, such duty resting exclusively with the manufacturer (Br. 30, 37); and (ii) the "method, mode and extent of compliance review is left by the regulations to the discretion of the FDA." (Br. 11, 29). The first of these is irrelevant; the second, wholly inaccurate.

Regarding the first, the issue here is not who *generates* the data on regulatory compliance. The issue is what is to be done—or more precisely, what the agency employee reviewing the license application is and *is not* empowered to do—on the *basis* of the data. Under the statute and regulations here, agency employees *are not authorized* to issue a license unless data submitted by the manufacturer demonstrate the vaccine's compliance with regulatory standards. This issue is absolutely unaffected by the fact that it is the manufacturer who performs the tests and generates the data upon which the licensing decision must be based.

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[12] The word "insure" is not inappropriate in this context. However, insuring compliance with the regulations does not make the government an insurer of the safety of the vaccine. As noted in the discussion *supra*, if the regulations, though followed, are not sufficient to prevent harm, the government is not liable.

As to the second point, the government's assertion that the scope of compliance review is left by the regulations to the discretion of agency employees is wholly inaccurate. The agency's regulations properly reflect the restrictive statutory mandate in directing that: "A product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations." 42 C.F.R. § 73.5. (SA-4). The standards applicable to live poliovirus vaccine are precisely defined in section 73.110, which states that the vaccine produced by an original poliovirus strain must meet the requirements of Sections 73.114(b) (safety, as defined by neurovirulence); 73.115 (potency); and 73.117 (antigenicity). The critical safety requirement, set forth in section 73.114, precisely defines neurovirulence by five discrete criteria which are reduced to numerical values.[13] The government's argument that this language can mean something less than compliance with *all* of the standards explicitly made applicable to the vaccine is, at best, disingenuous. In *Varig*, the regulatory plan specifically authorized "spot check" inspections and specifically empowered FAA employees to choose *not* to inspect, based on their subjective judgment of the manufacturer's reliability. Express power was conferred to issue a certificate whether or not regulatory compliance was demonstrated.[14] Implementing employees were thus authorized to exercise policy judgment in determining what standards to review, whether

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[13] The Brief of Lederle Laboratories as Amicus Curiae argues that this regulation is not mandatory because it involves "complex scientific determinations". (Br. 3-4). Scientific judgment is not policy judgment. Basic judgment *is* required to recognize that test results showing that the vaccine under review paralyzed one monkey demonstrate excessive neurovirulence, since the Reference strain paralyzed no monkeys. This judgment, however, is not within the category of "legislative and administrative decisions grounded in social, economic, and political policy" which are protected. This distinction was addressed at length by the district court in *Griffin*, *supra*, 351 F.Supp. at 30.

[14] 49 U.S.C. § 1421(c), set forth at n. 46, *Brief for Petitioners*.

to review at all, and whether to issue a certificate despite regulatory non-compliance. *No such authority is provided here.* Therefore, a directive to license *only* when regulatory standards are met cannot mean anything less than *all* standards. Test results submitted with the licensing application at issue here demonstrated that the vaccine violated the most critical requirement for licensing- the neurovirulence criteria. (J.A. 12, ¶ 17(g)). Unlike *Varig*, neither the statute nor the regulations here confer discretion to license *despite* demonstrated non-compliance.[15] The conduct here is not, therefore, protected by *Varig*.

The government's most remarkable attempt to avoid the mandatory grasp of these regulations is the argument that the regulations do not apply at all to the Sabin vaccine—that before the regulations were promulgated an independent committee found the vaccine to be "acceptable for use" (Br. 34); that this committee then "worked closely" with the department in formulating regulatory standards (Br. 35); and that "under these circumstances, new data on the Sabin strain clearly were not required by the regulations." (Br. 34). The government concludes that to contend that the Sabin vaccine does not meet criteria drafted "with it in mind" in untenable. (Br. 36) That this argument rests totally on extra-judicial "facts" will be put aside. There is no basis for exempting the Sabin vaccine from Congress' express mandate prohibiting the manufacture of vaccines without a federal license and authorizing the issuance of the

[15] The government points to 42 C.F.R. § 73.12, authorizing the Surgeon General to convene a special board "when deemed advisable" to review reports of inspections and laboratory examinations, and argues that this shows the agency's discretion to determine the scope of compliance review. (Br. 31). This section does not purport to change the requirements of licensing, but simply provides a mechanism for double-checking the process and gaining an overview of the effectiveness of agency procedures. That the Surgeon General is authorized to do *more* than the regulations require obviously does not mean that subordinate employees have discretion to do *less*.

license *only* upon a showing of regulatory compliance. If the government is correct, if in fact the requirements of the regulations do correspond with the demonstrated characteristics of the Sabin vaccine, that would provide a substantive defense at trial. It is *not* a basis for holding that regulatory compliance was not required.[16]

VI. Regarding the lot release approval, proof that the agency interpreted applicable regulations as mandatory in the circumstances presented here would entitle Petitioners to relief. The claim should not, therefore, be dismissed.

Regarding the lot release approval, dismissal of the claim is inappropriate because there are facts to be proven—the agency's own interpretation of applicable regulations as mandatory under the circumstances presented here—which would entitle Petitioners to relief. The threshold issue presented is whether the agency had a non-discretionary duty to evaluate the neurovirulence of individual monopools for regulaotry compliance and to prevent the release of a vaccine lot containing noncomplying monopools. 21 C.F.R. § 610.2, found in the introductory section of the regulations and not in the section specifically applying to live poliovirus vaccine, empowers the agency to hold vaccine lots for agency approval, but is not explicit regarding when agency approval is required. However, as applied to live poliovirus vaccines, testimony of record in the *Griffin* case demonstrated that

[16] This action is not, as the government contends, an attempt "to enter the Salk/Sabin debate on the side of Salk and to hold the government liable for coming out the otherway." (Br. 36). The allegation here has nothing to do with whether the Sabin vaccine was "safe" or whether Salk was "safer". The allegation is simply that the Sabin Type III vaccine did not comply with the agency's *regulatory definition* of safety and should not, therefore, have been licensed. Nor does this allegation threaten the government's vaccine program. There are, and were, Type III alternatives; the Sabin Type III vaccine at issue here has, in fact, been abandoned.

agency approval was required for *every* vaccine lot.[17] The Amicus Brief filed in support of the government by Lederle Laboratories states that, "Each batch of vaccine must be inspected both by the manufacturer *and by the government* before the manufacturer can release it for use, *and the government's decision is final.*" (Amicus Br. 2). Documents provided by Lederle Laboratories in discovery in other polio cases show a government stamp on *every* lot release form.

An agency's interpretation of its own regulations is entitled to deference, unless such interpretation is inconsistent with a statutory mandate or frustrates the policy Congress sought to implement. *Federal Election Committee v. Democratic Senatorial Campaign Committee*, 454 U.S. 27, 31-32 (1981). Agency policy requiring review of every live-virus vaccine lot for regulatory compliance prior to release would be fully *consistent* with Congress' expressed concern for the continuing safety of vaccines, particularly since live viruses may be genetically unstable and subject to change. The standard governing issuance of the lot release approval is demonstrated compliance with the neurovirulence criteria specifically set forth in the regulations.[18]

Further, even if the *decision* to test were found to be discretionary, whether protection extends to the implementing conduct—release of a vaccine lot which was known to be excessively neurovirulent—depends on whether the employee was acting "in accordance with

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[17] *Griffin, supra*, 500 F.2d at 1065, n.11 (government's brief describes "tests which the manufacturer must complete prior to the submission of a lot to DBS for release"; "DBS performed its own tests on every sample of vaccine submitted").

[18] 21 C.F.R. § 630.17(b). Further authority is cited in Petitioners' opening brief at 21. It should be noted here that 21 C.F.R. § 630.17(b) is set forth at SA-10. However, as the government has already noted (Br. 39, n. 36), the section number was omitted in typesetting, and the text appears to be part of the preceding regulation, § 610.2.

official directions", or alternatively, was an "employee exercising discretion". *Dalehite*, 346 U.S. at 33, 36.

Dismissal of this claim is appropriate only if it appears beyond doubt that Petitioners can prove no set of facts in support of the claim which would entitle them to relief. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). Because there do exist facts to be proven which would entitle Petitioners to relief, *e.g.*, agency interpretation of the regulation as mandatory under these circumstances, dismissal of the claim was error.

VII. The government's attempt to put facts in dispute illustrates the inappropriateness of dismissal of the case under Rule 12. The extra-judicial facts asserted by the government, even if accepted, do not alter the core question presented.

Among the government's factual contentions is the claim that a product license is issued only for the vaccine itself and is not required for a seed virus. (Br. 31-32.) At the same time, the government admits that seed viruses do require agency "approval." (Br. 36, n.33). This is the first time the government has contested the point. The issue was presented in identical terms to the court of appeals and was not disputed. In any event, whether the product for which a license is required is a virus strain, seed virus or vaccine does not change the core question presented—whether issuance of a license for a live poliovirus product which was known not to comply with regulatory safety standards is protected conduct. We contend that it is not, based on the principles enunciated in Petitioners' opening brief and discussed in the earlier sections of this brief. On this issue, the record presently before the Court compels the holding that: *under section 262(d) of the Public Health Service Act and following regulations, issuance of a license for a live poliovirus product which is not demonstrated to be in compliance with all regulatory requirements applicable to the product is not immune conduct under section 2680(a)*

of the Tort Claims Act. The licensing claim should proceed to trial.

Whether or not a license is required for a seed virus does affect one of the subsidiary issues presented, i.e., whether failure to revoke the license when the seed demonstrated a change in neurovirulence is actionable. It is obviously correct that if a license was not required for the seed virus, there can be no contention that the agency is liable for having failed to revoke it.[19] However, the government has admitted that agency "approval" *is* required for each seed virus. Under the circumstances presented, dismissal of the claim was error. Petitioners respectfully submit that this issue should be remanded with instructions to develop a factual record on the following points regarding the seed virus: (i) the nature of the required government approval; (ii) whether the principles governing the licensing issues should apply to resolution of the question whether the agency's "approval" of a non-complying seed virus is immunized conduct; and (iii) whether the requalification requirement of 42 C.F.R. § 73.110(b)(5) (SA-7) is a non-discretionary directive to revoke the "approval" when a change in the seed's neurovirulence has been demonstrated.

VIII. The National Childhood Vaccine Injury Act has no bearing on the issues presented here.

The government's argument that the Vaccine Act was intended to provide an exclusive remedy for vaccine injuries and otherwise demonstrates Congress' intent that

[19] The government confuses the revocation issue with the abandoned allegation that the agency was liable for failing to order the withdrawal of vaccines that had *already been released* for public distribution. (Br. 6, n.7). (*See, Brief for Petitioners*, 7, n. 18 for a summary of pertinent procedural history on this point.) The seed virus was never subject to release; it remained in the laboratory and in use for production of vaccine monopools. The allegation is that *before production* of the monopol that paralyzed Kevan, the seed demonstrated a change in neurovirulence, requiring that its license, or "approval", be revoked. These issues are entirely distinct.

tort actions against the government are barred is fallacious. First, as this Court has previously held, "there is nothing in the Tort Claims Act . . . which provides for exclusiveness of remedy." The Court cannot "pronounce a doctrine of election of remedies, when Congress has not done so." *Brooks v. United States*, 337 U.S. 49, 53 (1949). The Vaccine Act was not even passed until seven years after this litigation commenced and has no effect on the remedies available to Kevan Berkovitz. In fact, the Vaccine Act presently offers *no* remedy to *any* injured person, since it has never been funded. To argue that the Act presents any obstacle to the maintenance of this action is irresponsible.

As the government correctly notes, the Act was passed in response to threats by vaccine manufacturers to stop producing vaccines unless the government took steps to mitigate the manufacturers' potential liability for vaccine-related injuries. The central purpose of the Act was thus to appease private manufacturers in order to assure the continued availability of vaccines. The Act does not accomplish this purpose by erecting a bar to civil actions. Rather, section 2111(2) provides that the Act's no-fault administrative remedy must be pursued *before* civil actions against vaccine manufacturers may proceed, the premise being that injured persons will elect this "guaranteed compensation package" and voluntarily relinquish the "more uncertain remedy" available in tort. (Br. 43). The Act thus restrains, but does not prohibit, civil process against those entities which threaten the government's immunization policies, *i.e.*, vaccine manufacturers. The Act has no effect on civil actions against any parties outside that class, including physicians subject to liability for having administered the vaccine.

That the Act does not contain specific references to FTCA actions is, therefore, not surprising; the omission is fully consistent with the Act's exclusive protection of vaccine manufacturers. In such a context the government's argument that the Act is silent as to FTCA ac-

tions "presumably because Congress viewed the discretionary function exception as a bar to such suits" has no foundation.[20]

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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[20] The express waiver of the discretionary function exception in the swine flu legislation, 42 U.S.C. § 247b(k)(2) evinces an acceptance of liability for the policy judgment of the agency and would thus provide compensation when the agency's regulations, even though complied with, were not sufficient to protect against the harm of vaccine injury.

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No. 87-498

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Supreme Court of the United States
OCTOBER TERM, 1987

KEVAN BERKOVITZ, *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

MOTION FOR LEAVE TO FILE BRIEF AS AMICUS CURIAE AND BRIEF FOR LEDERLE LABORATORIES, A DIVISION OF AMERICAN CYANAMID CO. AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

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MOTION ON BEHALF OF LEDERLE LABORATORIES FOR LEAVE TO FILE BRIEF AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

Lederle Laboratories, a division of American Cyanamid Co., moves for leave to file a brief as amicus curiae in support of respondent, United States of America. The respondent has consented to the filing of this brief, and the petitioners have denied consent.

Lederle Laboratories is the manufacturer of Orimune®, the polio vaccine alleged to have been administered to petitioner Kevan Berkovitz. Petitioners' claims against Lederle Laboratories have been settled. However, the

legal standards governing tort liability in suits challenging the design and licensing of vaccines are of keen interest to Lederle Laboratories in its continuing efforts to make safe and effective vaccines available to the public at a reasonable price.

The Third Circuit in its opinion below stated that it is the vaccine manufacturer who has the primary responsibility for insuring compliance with the applicable FDA regulations. *Berkovitz v. United States*, No. 86-3444, slip op. at 23 (3d Cir. June 30, 1986). The purpose of Lederle's amicus brief is to inform the Court of some of the issues surrounding manufacturer's liability that are currently working their way through the lower federal courts, and to advise against the adoption of any such broad language that might unnecessarily prejudice the outcome of these cases.

Respectfully submitted,

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTEREST OF AMICUS CURIAE 1

ARGUMENT 2

I. THE STANDARDS GOVERNING A MANUFACTURER'S TORT LIABILITY FOR "REGULATORY NON-COMPLIANCE" RAISE COMPLEX QUESTIONS THAT ARE NOT DIRECTLY PRESENTED BY THIS CASE AND THAT SHOULD BE EXPLICITLY RESERVED FOR FUTURE DECISION 2

II. AN OVERLY BROAD IMPLICATION OF POTENTIAL TORT LIABILITY FOR VACCINE MANUFACTURERS WOULD UNDERMINE THE GOALS OF THE GOVERNMENT'S NATIONAL IMMUNIZATION POLICY 4

CONCLUSION 7

TABLE OF AUTHORITIES

CASES:	Page
Abbot v. American Cyanamid Co., No. 87-1578 (4th Cir.) (pending)	6
Abbot v. American Cyanamid Co., No. 86-857-A (E.D. Va. March 9, 1987)	6
Berkovitz v. United States, No. 86-3444, slip op. (3d Cir. June 30, 1986)	2
Hurley v. Lederle Laboratories, No. 87-2578 (5th Cir.) (pending)	6
Hurley v. Lederle Laboratories, 651 F. Supp. 993 (E.D. Tex. 1986)	6
Johnson v. American Cyanamid Co., 718 P.2d 1318 (Kan. 1986)	5
REGULATION:	
42 C.F.R. § 73.114 (1961)	3
CONGRESSIONAL MATERIAL:	
Childhood Immunizations, 99th Cong., 2d Sess. (Comm. Print 1986)	5
H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986)	5, 6
MISCELLANEOUS MATERIAL:	
Institute of Medicine, *Vaccine Supply and Innovation* (1985)	5

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BRIEF FOR LEDERLE LABORATORIES, A DIVISION OF AMERICAN CYANAMID CO. AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

This amicus curiae brief is submitted in support of respondent United States of America. By letter filed with the Clerk of the Court, the respondent has consented to the filing of this brief. However, petitioners have denied consent, and a motion for leave to file accompanies this brief.

INTEREST OF AMICUS CURIAE

Lederle Laboratories is the manufacturer of Orimune®, the polio vaccine alleged to have been administered to petitioner Kevan Berkovitz. Petitioners' claims against Lederle Laboratories have been settled. However, the

legal standards governing tort liability in suits challenging the design and licensing of vaccines are of keen interest to Lederle Laboratories in its continuing efforts to make safe and effective vaccines available to the public at a reasonable price.

ARGUMENT

I. THE STANDARDS GOVERNING A MANUFACTURER'S TORT LIABILITY FOR "REGULATORY NONCOMPLIANCE" RAISE COMPLEX QUESTIONS THAT ARE NOT DIRECTLY PRESENTED BY THIS CASE AND THAT SHOULD BE EXPLICITLY RESERVED FOR FUTURE DECISION.

Both the Third Circuit in its opinion below and the government in some of its briefs have suggested that it is the vaccine manufacturer, rather than the government, who is primarily responsible for insuring compliance with federal vaccine regulations.[1] In fact, the responsibility is a shared one. Each batch of vaccine must be inspected both by the manufacturer and by the government before the manufacturer can release it for use, and the government's decision is final.

Petitioners have attempted to portray the vaccine licensing regulations at issue in this case as setting compliance standards that are completely objective and mandatory. That portrayal is not correct. The actual process of selecting and licensing particular biological products (such as vaccines) is a highly discretionary exercise involving subjective evaluations of complicated scientific evidence. Neither the government nor the manufacturer should be subjected to tort judgments based on an after-the-fact second-guess of such complex evaluations.

Petitioners in this case suggest that the government made no subjective judgments when it decided to license Lederle's original virus strains:

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[1] *See, e.g., Berkovitz v. United States*, No. 86-3444, slip op. at 23 (3d Cir. June 30, 1986); Brief for Appellant at 34-35, *Berkovitz v. United States*, No. 86-3444 (3d Cir. June 30, 1986).

> No policy judgment is needed, for example, to determine whether two paralyzed Macaca monkeys is a greater number than none; whether three lesions are more than two; whether a lesion which advanced 2 cm beyond the point of inoculation has a greater spread than one which advanced .5 cm from the inoculation site.

Petitioners' Brief at 16. But petitioners misconstrue the regulations upon which these examples are based. The relevant regulation, 42 C.F.R. § 73.114(b)(1)(iii) [1961], provides:

> *Determination of neurovirulence.* At the conclusion of the observation period comparative histopathological examinations shall be made . . . of each monkey in the groups injected with virus under test and those injected with the NIH Reference Attenuated poliovirus . . . . A comparative evaluation shall be made of the evidence of neurovirulence of the virus under test and the NIH Reference Attenuated Poliovirus with respect to (a) the number of animals showing lesions characteristic of poliovirus infection, (b) the number of animals showing lesions other than those characteristic of poliovirus infection, (c) the severity of the lesions, (d) the degree of dissemination of the lesions, and (e) the rate of occurrence of paralysis not attributable to the mechanical injury resulting from inoculation trauma. The virus pool under test is satisfactory for poliovirus vaccine manufacture only if at least 80 percent of the animals in each group survive the observation period and if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the NIH Reference Attenuated Poliovirus.

These regulations do not involve objective tests that can be "passed" or "failed." Questions of the "severity" of the lesions under subpart (c) and whether particular lesions are "characteristic of poliovirus" under subparts (a) and (b), for example, involve complex scientific de-

terminations. The reviewer must engage in a subjective weighing of the available data, and must arrive at an overall conclusion as to whether the virus strain that was tested was more neurovirulent than the government's reference strain. The question of whether "a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the [government's reference strain]" is not an "objective" determination without room for discretion.

Vaccine manufacturers, as they must, rely on the government's interpretation of the requirements imposed by regulations like this one. The question whether a vaccine manufacturer should be subject to potentially destructive tort liability because a judge or lay jury concludes after the fact that both the manufacturer and the government were negligent in interpreting the results of such a test is a highly complex one. The government argues that its ability to make sound scientific and policy judgments would be impaired by exposure to tort liability. Lederle has similarly suggested that, if it is to continue participating in this crucial public health program, it must be able to rely on the government's judgments without fear that judges and juries in tort cases will reach different conclusions. There is no reason, on this record, for the Court to address that issue now, but neither should the Court complicate or prejudice its ultimate conclusions on that issue by adopting broad suggestions of a manufacturer's sole responsibility for regulatory compliance.

II. AN OVERLY BROAD IMPLICATION OF POTENTIAL TORT LIABILITY FOR VACCINE MANUFACTURERS WOULD UNDERMINE THE GOALS OF THE GOVERNMENT'S NATIONAL IMMUNIZATION POLICY.

The United States is in the midst of an unprecedented explosion of vaccine liability litigation. Hundreds of suits are pending, with damage claims totaling several billions

of dollars,[2] or about ten times the annual sales of the entire vaccine industry.[3] Many manufacturers have ceased making childhood vaccines because of their exposure to tort liability and their inability to obtain affordable liability insurance.[4]

The case at bar involves a heated scientific controversy over the live-cell Sabin oral polio vaccine, which the government's own authorities have selected as the polio vaccine of choice over the killed-cell Salk vaccine.[5] Some of the other pending cases are similar, and still others involve a related controversy about the vaccine selected by the government for immunization against diptheria, pertussis (whooping cough) and tetanus—the so-called DTP vaccine.

The pending DTP cases do not assert claims of government negligence in the licensure of the whole-cell DTP vaccine or in the approval of lots submitted for government testing. In many of these DTP suits, plaintiffs have asserted claims that a "design defect" requires imposition of liability on the vaccine manufacturer. The gist of these claims is that the defendant vaccine manufacturers (of which Lederle Laboratories is one) should have designed a different and less dangerous *type* of DTP

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[2] *Childhood Immunizations*, 99th Cong., 2d Sess. (Comm. Print 1986) at 85-86.

[3] Institute of Medicine, *Vaccine Supply and Innovation* (1985).

[4] H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986), Part 1, at 6-7. Wyeth Laboratories recently ceased supplying the diptheria, pertussis, tetanus vaccine, leaving only two domestic suppliers. Lederle is the sole supplier of the oral polio vaccine, and Merck Sharp & Dohme is the sole supplier of the measles, mumps, rebella vaccine.

[5] *See also Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1322 (Kan. 1986) (holding as a matter of law that there is no design defect in Lederle's Sabin live-cell oral polio vaccine because the Sabin-type of vaccine utilized by Lederele "was the vaccine of choice recommended by all major health organizations in the United States.").

vaccine than the type *selected and approved* by the federal government, even though the government itself maintains that the different type has not yet been shown to be safe and effective for use.[6] Lay juries are invited, in effect, to make a *de novo* determination of which theoretically available vaccine should have been developed by the manufacturer. The question whether federal law has a pre-emptive effect that would bar such *de novo* determinations is in fact now pending in two Courts of Appeals.[7]

"Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986), Part 1, at 4. It is indeed true, as the government asserts, that the imposition of tort liability on the government in suits such as *Berkovitz* poses a serious threat to the continuance of these spectacularly effective programs. *See* Brief for the United States in Support of Petition for Certiorari at 8, *Berkovitz v. United States*, No. 87-498 (Dec. 1987). A decision by a lay jury that the government negligently licensed the only vaccine available to prevent a deadly childhood disease could leave the nation without any way of protecting its children. Too broad an imposition of tort liability against vaccine manufacturers could have an equally devastating effect. Any implication of sole and

[6] Brief of United States as Amicus Curiae, *Abbot v. American Cyanamid Co.*, No. 87-1578 (4th Cir.) (pending) ("based on their evaluation of the available scientific and medical evidence, HHS's public health experts have concluded that alternative pertussis vaccines have not yet been adequately shown to be safe and effective for licensure in the United States.").

[7] *Abbot v. American Cyanamid Co.*, No. 87-1578 (4th Cir.) (pending), *reviewing* No. 86-857-A (E.D. Va. March 9, 1987) (finding preemption); *Hurley v. Lederle Laboratories*, No. 87-2578 (5th Cir.) (pending), *reviewing* 651 F. Supp. 993 (E.D. Tex. 1986) (finding preemption).

potentially unlimited responsibility on the part of vaccine manufacturers who follow the government's lead or rely on the government's subjective interpretations of its own regulatory requirements could undermine or destroy these life-saving programs.

CONCLUSION

In *Berkovitz* the Court is called upon to decide only whether the discretionary function doctrine protects the federal government from exposure to tort liability for the alleged negligence of its employees in failing to follow its own regulatory guidelines. We submit that in making this determination, the Court should not intimate or infer that liability in such circumstances rests on the vaccine manufacturer.

Respectfully submitted,

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